

# Oracle® Process Manufacturing

Regulatory Management User's Guide

Release 11*i*

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Oracle Process Manufacturing Regulatory Management User's Guide, Release 11i

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# Send Us Your Comments

**Oracle Process Manufacturing Regulatory Management User's Guide, Release 11i**

**Part No. A81210-08**

Oracle welcomes your comments and suggestions on the quality and usefulness of this document. Your input is an important part of the information used for revision.

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If you have problems with the software, please contact your local Oracle Support Services.



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# Preface

Welcome to the Oracle Process Manufacturing Regulatory Management User's Guide, Release 11i.

This guide assumes you have a working knowledge of the following:

- The principles and customary practices of your business area.
- Regulatory Management and Oracle Process Manufacturing.

If you have never used Oracle Receivables or Oracle Process Manufacturing, Oracle suggests you attend one or more of the Oracle Applications training classes available through Oracle University.

- Oracle Self-Service Web Applications.

To learn more about Oracle Self-Service Web Applications, read the *Oracle Self-Service Web Applications Implementation Manual*.

- The Oracle Applications graphical user interface.

To learn more about the Oracle Applications graphical user interface, read the *Oracle Applications User's Guide*.

See [Other Information Sources](#) for more information about Oracle Applications product information.

## How To Use This Guide

The Oracle Process Manufacturing Regulatory Management User's Guide contains the information you need to understand and use Oracle Process Manufacturing. This guide contains four chapters:

- [Chapter 1](#) Regulatory Management Overview, explains how OPM Regulatory Management is used and gives general features of Regulatory Management.
- [Chapter 2](#) Document Management, describes uploading external documents such as Material Safety Data Sheets (MSDS) Phrasing Subscriptions using Files Approval System. Using Oracle E-Records and setting up Oracle Approvals Management (AME) are also explained.
- [Chapter 4](#) Setting Up Regulatory Management, explains the Regulatory Management Setup requirements.
- [Chapter 3](#) Defining Regulatory Item Information, explains how to manage the items that you report hazard information for based on your particular reporting requirements. Hazard information can be assigned to either products or ingredients, or both.
- [Chapter 5](#) Running Regulatory Management Reports, explains the available OPM Regulatory Management reports.
- [Appendix A](#) provides navigation paths and specific Profile Options that need to be set up in Regulatory Management.
- [Glossary](#) defines a list of terms used in Regulatory Management.

## **Documentation Accessibility**

Our goal is to make Oracle products, services, and supporting documentation accessible, with good usability, to the disabled community. To that end, our documentation includes features that make information available to users of assistive technology. This documentation is available in HTML format, and contains markup to facilitate access by the disabled community. Standards will continue to evolve over time, and Oracle is actively engaged with other market-leading technology vendors to address technical obstacles so that our documentation can be accessible to all of our customers. For additional information, visit the Oracle Accessibility Program Web site at <http://www.oracle.com/accessibility/>

### **Accessibility of Code Examples in Documentation**

JAWS, a Windows screen reader, may not always correctly read the code examples in this document. The conventions for writing code require that closing braces should appear on an otherwise empty line; however, JAWS may not always read a line of text that consists solely of a bracket or brace.

### **Accessibility of Links to External Web Sites in Documentation**

This documentation may contain links to Web sites of other companies or organizations that Oracle does not own or control. Oracle neither evaluates nor makes any representations regarding the accessibility of these Web sites.

## Other Information Sources

You can choose from many sources of information, including documentation, training, and support services, to increase your knowledge and understanding of Oracle Process Manufacturing.

If this guide refers you to other Oracle Applications documentation, use only the Release 11*i* versions of those guides.

### Online Documentation

All Oracle Applications documentation is available online (HTML or PDF).

- **PDF Documentation**- See the Online Documentation CD for current PDF documentation for your product with each release. This Documentation CD is also available on Oracle*MetaLink* and is updated frequently.
- **Online Help** - You can refer to Oracle Applications Help for current HTML online help for your product. Oracle provides patchable online help, which you can apply to your system for updated implementation and end user documentation. No system downtime is required to apply online help.
- **Release Content Document** - See the Release Content Document for descriptions of new features available by release. The Release Content Document is available on Oracle*MetaLink*.
- **About document** - Refer to the About document for information about your release, including feature updates, installation information, and new documentation or documentation patches that you can download. The About document is available on Oracle*MetaLink*.

### Related Guides

Oracle Process Manufacturing shares business and setup information with other Oracle Applications products. Therefore, you may want to refer to other guides when you set up and use Oracle Process Manufacturing.

You can read the guides online by choosing Library from the expandable menu on your HTML help window, by reading from the Oracle Applications Document Library CD included in your media pack, or by using a Web browser with a URL that your system administrator provides.

If you require printed guides, you can purchase them from the Oracle Store at <http://oraclestore.oracle.com>.

## Guides Related to All Products

### **Oracle Applications User's Guide**

This guide explains how to enter data, query, run reports, and navigate using the graphical user interface (GUI). This guide also includes information on setting user profiles, as well as running and reviewing reports and concurrent processes.

You can access this user's guide online by choosing "Getting Started with Oracle Applications" from any Oracle Applications help file.

## Guides Related to This Product

### **Accounting Setup User's Guide**

The OPM Accounting Setup application is where users set up global accounting attributes about the way financial data will be collected by OPM. These attributes include such things as account keys, financial calendars, and account segments. Since OPM is closely integrated with Oracle General Ledger (GL), much of the attributes are defined in the Oracle GL instead of OPM, and therefore, the windows are display only within OPM. The *Oracle Process Manufacturing Accounting Setup User's Guide* describes how to setup and use this application.

### **Cost Management User's Guide**

The OPM Cost Management application is used by cost accountants to capture and review the manufacturing costs incurred in their process manufacturing businesses. The *Oracle Process Manufacturing Cost Management User's Guide* describes how to setup and use this application.

### **Manufacturing Accounting Controller User's Guide**

The Manufacturing Accounting Controller application is where users define the impact of manufacturing events on financials. For example, event RCPT (Inventory Receipts) results in a debit to inventory, a credit to accrued accounts payable, a debit or a credit to purchase price variance, etc. These impacts are predefined in the Manufacturing Accounting Controller application so users may begin using OPM to collect financial data out-of-the-box, however, they may also be adjusted per your business needs. The *Oracle Process Manufacturing Manufacturing Accounting Controller User's Guide* describes how to setup and use this application.

## **Oracle Financials Integration User's Guide**

Since OPM is closely integrated with Oracle General Ledger, financial data that is collected about the manufacturing processes must be transferred to the Oracle Financials applications. The OPM Oracle Financials Integration application is where users define how that data is transferred. For example, users define whether data is transferred real time or batched and transferred at intervals. The *Oracle Process Manufacturing Oracle Financials Integration User's Guide* describes how to setup and use this application.

## **Inventory Management User's Guide**

The OPM Inventory Management application is where data about the items purchased for, consumed during, and created as a result of the manufacturing process are tracked. The *Oracle Process Manufacturing Inventory Management User's Guide* includes information to help you effectively work with the Oracle Process Manufacturing Inventory application.

## **Physical Inventory User's Guide**

Performing physical inventory count is the most accurate way to get an accounting of all material quantities purchased, manufactured, and sold, and update your onhand quantities accordingly. The OPM Physical Inventory application automates and enables the physical inventory process. The *Oracle Process Manufacturing Physical Inventory User's Guide* describes how to setup and use this application.

## **Order Fulfillment User's Guide**

The OPM Order Fulfillment application automates sales order entry to reduce order cycle time. Order Fulfillment enables order entry personnel to inform customers of scheduled delivery dates and pricing. The *Oracle Process Manufacturing Order Fulfillment User's Guide* describes how to setup and use this application.

## **Purchase Management User's Guide**

OPM Purchase Management and Oracle Purchasing combine to provide an integrated solution for Process Manufacturing. Purchase orders are entered in Oracle Purchasing and received in OPM. Then, the receipts entered in OPM are sent to Oracle Purchasing. The *Oracle Process Manufacturing Purchase Management User's Guide* describes how to setup and use this integrated solution.

## **Using Oracle Order Management with Process Inventory Guide**

Oracle Process Manufacturing and Oracle Order Management combine to provide an integrated solution for process manufacturers. The manufacturing process is tracked and handled within Oracle Process Manufacturing, while sales orders are taken and tracked in Oracle Order Management. Process attributes, such as dual UOM and lot control, are enabled depending on the inventory organization for the item on the sales order. Order Management accepts orders entered through Oracle Customer Relationship Management (CRM). Within CRM, orders can originate from TeleSales, Sales Online, and iStore, and are booked in Order Management, making the CRM suite of products available to Process customers, through Order Management. The *Oracle Order Management User's Guide* and *Using Oracle Order Management with Process Inventory Guide* describes how to setup and use this integrated solution.

## **Process Execution User's Guide**

The OPM Process Execution application lets you track firm planned orders and production batches from incoming materials through finished goods. Seamlessly integrated to the Product Development application, Process Execution lets you convert firm planned orders to single or multiple production batches, allocate ingredients, record actual ingredient usage, and then complete and close production batches. Production inquiries and preformatted reports help you optimize inventory costs while maintaining a high level of customer satisfaction with on-time delivery of high quality products. The *OPM Process Execution User's Guide* presents overviews of the tasks and responsibilities for the Production Supervisor and the Production Operator. It provides prerequisite setup in other applications, and details the windows, features, and functionality of the OPM Process Execution application.

## **Using Oracle Advanced Planning and Scheduling with Oracle Process Manufacturing**

Oracle Process Manufacturing and Oracle Advanced Planning and Scheduling (APS) combine to provide a solution for process manufacturers that can help increase planning efficiency. This solution provides for constraint-based planning, performance management, materials management by exception, mixed mode manufacturing that enables you to choose the best method to produce each of your products, and combine all of these methods within the same plant/company. The *Using Oracle Advanced Planning and Scheduling with Oracle Process Manufacturing User's Guide* describes how to setup and use this application.

## **MPS/MRP and Forecasting User's Guide**

The Oracle Process Manufacturing Material Requirements Planning (MRP) application provides long-term "views" of material demands and projected supply actions to satisfy those demands. The Master Production Scheduling (MPS) application lets you shorten that view to a much narrower and immediate time horizon, and see the immediate effects of demand and supply actions. The *Oracle Process Manufacturing MPS/MRP and Forecasting User's Guide* describes how to setup and use this application.

## **Capacity Planning User's Guide**

The OPM Capacity Planning User's Guide describes the setup required to use OPM with the Oracle Applications Advanced Supply Chain Planning solutions. In addition, Resource setup, used by the OPM Production Execution and New Product Development applications, is also described.

## **Using Oracle Process Manufacturing with Oracle Manufacturing Scheduling**

Oracle Process Manufacturing integrates with Oracle Manufacturing Scheduling to manage and utilize resources and materials. Through the Process Manufacturing application, you set up manufacturing, inventory, procurement and sales order data. Through the Manufacturing Scheduling application, you can optimize the schedule based on resource and component constraints and user predefined priorities. Using different optimization objectives, you can tailor Manufacturing Scheduling to meet your needs.

Using Oracle Manufacturing Scheduling helps you improve productivity and efficiency on your shop floor. By optimally scheduling shop floor jobs, and being able to quickly react to unplanned constraints, you can lower manufacturing costs, increase resource utilization and efficiency, and increase customer satisfaction through improved on-time delivery. The *Using Oracle Process Manufacturing with Oracle Manufacturing Scheduling User's Guide* describes how to setup and use this integrated solution.

## **Product Development User's Guide**

The Oracle Process Manufacturing Product Development application provides features to manage formula and laboratory work within the process manufacturing operation. It lets you manage multiple laboratory organizations and support varying product lines throughout the organization. You can characterize and simulate the technical properties of ingredients and their effects on formulas. You can optimize formulations before beginning expensive laboratory test batches. Product Development coordinates each development function and enables a rapid,

enterprise-wide implementation of new products in your plants. The *Oracle Process Manufacturing Product Development User's Guide* describes how to setup and use this application.

### **Quality Management User's Guide**

The Oracle Process Manufacturing Quality Management application provides features to test material sampled from inventory, production, or receipts from external suppliers. The application lets you enter specifications and control their use throughout the enterprise. Customized workflows and electronic record keeping automate plans for sampling, testing, and result processing. You can compare specifications to assist in regrading items, and match customer specifications. Aggregate test results and print statistical assessments on quality certificates. Several preformatted reports and inquiries help manage quality testing and reporting. The *Oracle Process Manufacturing Quality Management User's Guide* describes how to set up and use this application.

### **Implementation Guide**

The *Oracle Process Manufacturing Implementation Guide* offers information on setup. That is, those tasks you must complete following the initial installation of the Oracle Process Manufacturing software. Any tasks that must be completed in order to use the system out-of-the-box are included in this manual.

### **System Administration User's Guide**

Much of the System Administration duties are performed at the Oracle Applications level, and are therefore described in the *Oracle Applications System Administrator's Guide*. The *Oracle Process Manufacturing System Administration User's Guide* provides information on the few tasks that are specific to OPM. It offers information on performing OPM file purge and archive, and maintaining such things as responsibilities, units of measure, and organizations.

### **API User's Guides**

Public Application Programming Interfaces (APIs) are available for use with different areas of the Oracle Process Manufacturing application. APIs make it possible to pass information into and out of the application, bypassing the user interface. Use of these APIs is documented in individual manuals such as the *Oracle Process Manufacturing Inventory API User's Guide*, *Oracle Process Manufacturing Process Execution API User's Guide*, *Oracle Process Manufacturing Product Development Formula API User's Guide*, *Oracle Process Manufacturing Product Development Recipe API User's Guide*, *Oracle Process Manufacturing Quality Management API User's Guide*,

and the *Oracle Process Manufacturing Cost Management API User's Guide*. Additional API User's Guides are periodically added as additional public APIs are made available

## Installation and System Administration

### **Oracle Applications Concepts**

This guide provides an introduction to the concepts, features, technology stack, architecture, and terminology for Oracle Applications Release 11*i*. It provides a useful first book to read before an installation of Oracle Applications. This guide also introduces the concepts behind Applications-wide features such as Business Intelligence (BIS), languages and character sets, and Self-Service Web Applications.

### **Installing Oracle Applications**

This guide provides instructions for managing the installation of Oracle Applications products. In Release 11*i*, much of the installation process is handled using Oracle Rapid Install, which minimizes the time to install Oracle Applications and the Oracle technology stack by automating many of the required steps. This guide contains instructions for using Oracle Rapid Install and lists the tasks you need to perform to finish your installation. You should use this guide in conjunction with individual product user guides and implementation guides.

### **Upgrading Oracle Applications**

Refer to this guide if you are upgrading your Oracle Applications Release 10.7 or Release 11.0 products to Release 11*i*. This guide describes the upgrade process and lists database and product-specific upgrade tasks. You must be either at Release 10.7 (NCA, SmartClient, or character mode) or Release 11.0, to upgrade to Release 11*i*. You cannot upgrade to Release 11*i* directly from releases prior to 10.7.

### **“About” Document**

For information about implementation and user documentation, instructions for applying patches, new and changed setup steps, and descriptions of software updates, refer to the “About” document for your product. “About” documents are available on *OracleMetaLink* for most products starting with Release 11.5.8.

### **Maintaining Oracle Applications**

Use this guide to help you run the various AD utilities, such as AutoUpgrade, AutoPatch, AD Administration, AD Controller, AD Relink, License Manager, and

others. It contains how-to steps, screenshots, and other information that you need to run the AD utilities. This guide also provides information on maintaining the Oracle applications file system and database.

### **Oracle Applications System Administrator's Guide**

This guide provides planning and reference information for the Oracle Applications System Administrator. It contains information on how to define security, customize menus and online help, and manage concurrent processing.

### **Oracle Alert User's Guide**

This guide explains how to define periodic and event alerts to monitor the status of your Oracle Applications data.

### **Oracle Applications Developer's Guide**

This guide contains the coding standards followed by the Oracle Applications development staff and describes the Oracle Application Object Library components that are needed to implement the Oracle Applications user interface described in the *Oracle Applications User Interface Standards for Forms-Based Products*. This manual also provides information to help you build your custom Oracle Forms Developer forms so that the forms integrate with Oracle Applications.

### **Oracle Applications User Interface Standards for Forms-Based Products**

This guide contains the user interface (UI) standards followed by the Oracle Applications development staff. It describes the UI for the Oracle Applications products and how to apply this UI to the design of an application built by using Oracle Forms.

## **Other Implementation Documentation**

### **Oracle Applications Product Update Notes**

Use this guide as a reference for upgrading an installation of Oracle Applications. It provides a history of the changes to individual Oracle Applications products between Release 11.0 and Release 11*i*. It includes new features, enhancements, and changes made to database objects, profile options, and seed data for this interval.

## **Oracle Workflow Administrator's Guide**

This guide explains how to complete the setup steps necessary for any Oracle Applications product that includes workflow-enabled processes, as well as how to monitor the progress of runtime workflow processes.

## **Oracle Workflow Developer's Guide**

This guide explains how to define new workflow business processes and customize existing Oracle Applications-embedded workflow processes. It also describes how to define and customize business events and event subscriptions.

## **Oracle Workflow User's Guide**

This guide describes how Oracle Applications users can view and respond to workflow notifications and monitor the progress of their workflow processes.

## **Oracle Workflow API Reference**

This guide describes the APIs provided for developers and administrators to access Oracle Workflow.

## **Oracle Applications Flexfields Guide**

This guide provides flexfields planning, setup and reference information for the Oracle Process Manufacturing implementation team, as well as for users responsible for the ongoing maintenance of Oracle Applications product data. This guide also provides information on creating custom reports on flexfields data.

## **Oracle eTechnical Reference Manuals**

Each eTechnical Reference Manual (eTRM) contains database diagrams and a detailed description of database tables, forms, reports, and programs for a specific Oracle Applications product. This information helps you convert data from your existing applications, integrate Oracle Applications data with non-Oracle applications, and write custom reports for Oracle Applications products. Oracle eTRM is available on Oracle *Metalink*

## **Oracle Applications Message Manual**

This manual describes all Oracle Applications messages. This manual is available in HTML format on the documentation CD-ROM for Release 11*i*.

# Training and Support

## **Training**

Oracle offers a complete set of training courses to help you and your staff master Oracle Process Manufacturing and reach full productivity quickly. These courses are organized into functional learning paths, so you take only those courses appropriate to your job or area of responsibility.

You have a choice of educational environments. You can attend courses offered by Oracle University at any one of our many education centers, you can arrange for our trainers to teach at your facility, or you can use Oracle Learning Network (OLN), Oracle University's online education utility. In addition, Oracle training professionals can tailor standard courses or develop custom courses to meet your needs. For example, you may want to use your organization structure, terminology, and data as examples in a customized training session delivered at your own facility.

## **Support**

From on-site support to central support, our team of experienced professionals provides the help and information you need to keep Oracle Process Manufacturing working for you. This team includes your technical representative, account manager, and Oracle's large staff of consultants and support specialists with expertise in your business area, managing an Oracle server, and your hardware and software environment.

## Do Not Use Database Tools to Modify Oracle Applications Data

***Oracle STRONGLY RECOMMENDS that you never use SQL\*Plus, Oracle Data Browser, database triggers, or any other tool to modify Oracle Applications data unless otherwise instructed.***

Oracle provides powerful tools you can use to create, store, change, retrieve, and maintain information in an Oracle database. But if you use Oracle tools such as SQL\*Plus to modify Oracle Applications data, you risk destroying the integrity of your data and you lose the ability to audit changes to your data.

Because Oracle Applications tables are interrelated, any change you make using Oracle Applications can update many tables at once. But when you modify Oracle Applications data using anything other than Oracle Applications, you may change a row in one table without making corresponding changes in related tables. If your tables get out of synchronization with each other, you risk retrieving erroneous information and you risk unpredictable results throughout Oracle Applications.

When you use Oracle Applications to modify your data, Oracle Applications automatically checks that your changes are valid. Oracle Applications also keeps track of who changes information. If you enter information into database tables using database tools, you may store invalid information. You also lose the ability to track who has changed your information because SQL\*Plus and other database tools do not keep a record of changes.

## About Oracle

Oracle develops and markets an integrated line of software products for database management, applications development, decision support, and office automation, as well as Oracle Applications, an integrated suite of more than 160 software modules for financial management, supply chain management, manufacturing, project systems, human resources and customer relationship management.

Oracle products are available for mainframes, minicomputers, personal computers, network computers and personal digital assistants, allowing organizations to integrate different computers, different operating systems, different networks, and even different database management systems, into a single, unified computing and information resource.

Oracle is the world's leading supplier of software for information management, and the world's second largest software company. Oracle offers its database, tools, and applications products, along with related consulting, education, and support services, in over 145 countries around the world.

## Your Feedback

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Oracle values your comments and feedback. In this guide is a reader's comment form that you can use to explain what you like or dislike about Oracle Process Manufacturing or this user guide. Mail your comments to the following address or call us directly at (650) 506-7000.

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Oracle Corporation  
500 Oracle Parkway  
Redwood Shores, CA 94065  
U.S.A.

Or, send electronic mail to [appsdoc\\_us@oracle.com](mailto:appsdoc_us@oracle.com).



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# Regulatory Management Overview

This topic explains setting up regulatory management and the document management process.

The following topics are covered:

- [Regulatory Management Processes](#)
- [Setting Up Regulatory Management](#)

## Regulatory Management Processes

Using OPM Regulatory Management, upload documents that you are required to provide to customers when you supply hazardous materials. Create documents from the items that you set up in Regulatory Management. The actual document is not created in Regulatory Management; it is created in a third party product. In addition, you can generate documents for generic items by assigning OPM Inventory Management Item Master items to a Regulatory Management generic item.

Formula explosions can be printed on documents based on your specifications. Formulas with Production effectivities display all ingredients, and those with Regulatory effectivities show only those ingredients that you are required to report.

### Multilingual Support

The OPM Regulatory Management application supports multilingual data. Use any single character set that you require such as Western European or Eastern European. However, if you require multiple character sets, use a common character set, such as the UTF8 character set.

If you are upgrading from Oracle Applications or Oracle Process Manufacturing applications versions prior to release 11*i* and are implementing a different character set, verify that your data is not truncated or corrupted. Generally, text requires more space when it is converted to the UTF8 character set. However, each character set has its own conversion characteristics.

See: *Oracle Applications Installation Manuals*

Set up the following data in every language that you require:

- Hazard Classifications
- Field Names
- Field Name Classes
- Properties and Property Values
- Risk and Safety Phrases
- Item Groups
- Item and Generic Item Multilingual Names

### **Seed Data**

The OPM Regulatory Management application seeds basic information to ease implementation. The following items are seeded:

- Field Names
- Property
- Field Name Classes
- Risk and Safety Phrases
- Standard Disclosure Code

## Setting Up Regulatory Management

Following is the process for setting up OPM Regulatory Management:

1. Set up organizations, customers, responsibilities, languages, and profile options in Oracle Applications.
2. Set up items in OPM Inventory Management.
3. Set up formulas in Formulator.
4. Complete Regulatory Management Setup in order, then items.

Print the Reports

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## Document Management

This topic shows how to upload external documents such as Material Safety Data Sheets (MSDS) Phrasing Subscriptions using Files Approval System. Using Oracle E-Records and setting up Oracle Approvals Management (AME) are also explained.

The following topics are covered:

- [Solutions](#)
- [Understanding Document Management](#)
- [Setting Up Oracle Approvals Management](#)
- [Using the Evidence Store](#)
- [Uploading Regulatory Documents](#)

## Solutions

**Provide Document Approvals** OPM Product Development enables both new and updated documents to be routed through an approval process before being published or distributed. The approval process supports the entry and management of 21 CFR Part 11 compliant e-signatures. This signature must contain two distinct components. The Oracle E-Business Suite uses the user ID and password for the approval process.

**Attach Regulatory Documents to Regulatory Items** OPM Regulatory Management stores MSDS and regulatory documents associated to an OPM record in Oracle E-Records which provides full audit trail and CFR compliance tracking. The documents can be sourced internally, or they can be gathered externally from Regulatory MSDS Hazardous Phrase Subscription providers. Attaching or modifying documents is controlled through iSign Files Approval.

## Understanding Document Management

Optionally, Oracle Workflow enables regulatory documents to be submitted for approval before they are made available for general distribution. Approvers are defined in AME.

Oracle E-Records provides an interface that lets you search and display historical versions of a document. Search by document name, category, author, or status. You can also display user-defined values for each document based on the document category. And, you can search by user-defined values.

You can attach approved regulatory documents to a regulatory item. Only the most recent version of each approved document can be attached to a regulatory item. View historical versions from the Oracle E-Record Evidence store.

## Setting Up Oracle Approvals Management

Oracle Approvals Management is a self-service web application that lets you define business rules governing the process for approving transactions in other Oracle Applications. The purpose of AME is to define approval rules that determine the approval processes for Oracle Applications. Rules are constructed from conditions and approvals.

Create transaction attributes, conditions, approval groups, and approval rules within AME. The appropriate approvers are determined using the document category in iSign Files Approval.

### See Also

*Oracle Approvals Management User's Guide*

## Using the Evidence Store

E-records are stored in an evidence store. The evidence store provides a secure storage location and links to transaction windows. You can query the e-records repository using the evidence store. The Evidence Store window is divided into two regions. The top region lets you specify the query criteria and the bottom region shows the results of the query.

### See Also

*Oracle E-Records Implementation Guide*

## Uploading Regulatory Documents

You can upload external documents such as MSDS Phrasing Subscriptions using the iSign Files Approval. Each document is assigned a category that contains rules for the approval process. Each category has fifteen descriptive flexfield segments that are used to store information about the documents in that category. This information is stored in the database with the document, and can be used to search for the document.

Following are the four seeded Regulatory MSDS document categories used to determine the appropriate approvers:

- MSDS for a Regulatory Item
- MSDS for an Inventory Item
- MSDS for a Sales Order
- MSDS for a Recipient

### See Also

*Oracle Approvals Management User's Guide*

*Oracle E-Records Implementation Guide*

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## Defining Regulatory Item Information

OPM Regulatory Management Items lets you manage the items that you report hazard information for based on your particular reporting requirements. You can assign hazard information to either products, ingredients, or both.

- The Item Information navigator lets you define and maintain hazard information for products and ingredients in OPM Regulatory Management. Create new products and ingredients or use those that exist in the OPM Inventory Management Item Master.
- The Master Items Template lets you define and maintain OPM Regulatory Management generic item names and their associated OPM Inventory Management item names.

Copy existing items to create new items that are not already defined in OPM Regulatory Management or create new items. You can add, edit, delete, and report on items.

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**Note:** Regulatory Item Information can be viewed from within formulas and recipes.

See: *Oracle Process Manufacturing Product Development User's Guide*

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The following topics are covered:

- [Defining Regulatory General Item Information for New Items](#)
- [Defining Regulatory General Item Information for Existing Items](#)
- [Defining Regulatory Item Detail Information](#)
- [Item Information Navigator Reference](#)

- [Defining Master Item Associations](#)

## Defining Prerequisites

Define the following in OPM Regulatory Management Setup before defining items:

- Define languages before defining field names.  
*See: Oracle Applications User's Guide*
- Define product classes before defining items.
- Define disclosure codes.
- Define field name information, including field name class responsibilities, before defining items. Field name information determines the nodes displayed on the Item Information navigator and who has access to those nodes.
- Define European information before defining items.
- Define item group codes before defining items.

## Defining Regulatory Item Information Procedure

To enter item information:

1. Navigate to the **Find Regulatory Items** window.
2. Perform one of the following:
  - Click **New** to enter a new item. The General Item Information window is displayed.
  - Query the existing item to view or edit.
3. Perform one of the following:
  - If you are entering a new item, then complete the fields on the General Item Information window as described and go to step 4.
  - If you have located the existing item that you want, then go to step 4.
4. Click **Regulatory Item Detail**. The Regulatory Information window is displayed with the Item Information navigator active.
5. Complete, view, or edit the information on the Item Information navigator as described.
6. Save the window.

## Defining Regulatory General Item Information for New Items

Use the General Item Information window to define and maintain item hazard information for products and ingredients in Regulatory Management. You can add, edit, delete, and report on items.

### Defining Regulatory General Item Information for New Items Procedure

To enter general item information for new items:

1. Navigate to the **Find Regulatory Items** window.
2. Click **New** to enter a new item. The General Item Information window displays.
3. Complete the fields as described.
4. Click **Regulatory Item Detail** to continue. The Regulatory Information window is displayed with the Item Information navigator active.

### General Item Information for New Items Field Reference

The fields on this window are:

#### **Item Code**

Enter the code that identifies the Regulatory item. You can select items from the OPM Inventory Management Item Master or enter new ones. New items entered here exist only in Regulatory Management, not in the Inventory Management Item Master. Required.

#### **Primary CAS Number**

Enter the CAS (Chemical Abstracts Service Chemical Registry System) Number. The American Chemical Society's Chemical Abstract Service assigns CAS numbers.

The format for CAS numbers is *XXXXXX-XX-X*. While the format example shows the maximum number of digits for a CAS number, the first section of the number can be from a minimum of 2 digits to a maximum of 6 digits.

#### **Regulatory Item Creator**

Enter the item creator. Defaults to the user name that you are logged in as. Required.

**Product Class**

If the item is a member of a product class, enter that product class code. Field names excluded from that product class are not displayed on the Item Information navigator.

**Item Group Code**

If the item is a member of an item group, then enter that item group code.

**Internal Reference Number**

Enter a unique reference number to display on the document for the item. Informational only.

**Product Label Code**

For future use.

**Item Version**

Enter the revision number of the item to reflect that changes were made.

**Previous Item Version**

Displays the prior revision number of the item before the latest changes were made.

**Actual Hazard**

Available when the Ingredient check box is selected and the Explode Ingredients check box is cleared. Unavailable when both Ingredient and Explode Ingredients are selected or both are cleared.

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**Caution:** The ingredient is reduced based on this percentage for components that are not 100% hazardous.

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Enter the percentage of the item that is hazardous. The default is 100% when you select the Explode Ingredient check box to break the ingredient into its components. To calculate the percentage from OPM Regulatory Management or OPM Product Development, leave the actual hazard percentage at 100. Required.

**Ingredient**

- Clear if the item is a product. Default.

- Select if this item is an ingredient at its lowest level in the formula.

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**Note:** A formula must exist in either the Formulator or Regulatory Management applications for any ingredient that you plan to explode.

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### **Explode Ingredient**

Available when the ingredient check box is selected.

- Clear if the ingredient is at its lowest level in the formula. Default.
- Select to explode the ingredient into its components.

### **Formula Source Indicator**

Select the application where the formula explosion information is located for the ingredient or product. This formula is used for reporting 100% of the substances that make up the ingredient or product in MSDS Section 2. Required.

- **Formula.** An item that contains a formula in Product Development that can be broken down into components.
- **Stand Alone.** An item in only Regulatory Management that can be broken down into components.
- **No Formula.** An ingredient at its lowest level, whether it is part of a formula or a standalone item.

Formulas are exploded based on the recipes and validity rules associated with them. When Production Formula is selected as the Formula Source Indicator, components are exploded based on the existing active Regulatory or Product Development recipe and validity rules or both. The validity rule precedence is:

1. Regulatory validity rule for the default organization
2. Regulatory validity rule with no organization specified
3. Production validity rule for the default organization
4. Production validity rule with no organization specified

The organization specified in the validity rule must match the organization specified in the GR: Default Organization Code profile option.

See: *Oracle Process Manufacturing Product Development User's Guide*

[ ]

The double brackets ( [ ] ) identify a descriptive flexfield that you can use to add data fields to this window without programming. This descriptive flexfield lets you add your own information to the item.

## MSDS Names

### Language

Enter a valid language description. Enter every language that you create item documents for. Required.

### Description

Enter the item name in the selected language.

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**Note:** MSDS names are listed on the Multilingual Descriptions node on the Item Information Navigator. After creating an item, you can add or edit your list there.

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[ ]

The double brackets ( [ ] ) identify a descriptive flexfield that you can use to add data fields to this window without programming. This descriptive flexfield lets you add your own information to the item.

## Defining Regulatory General Item Information for Existing Items

Use the General Item Information window to define and maintain item hazard information for products and ingredients in Regulatory Management. You can add, edit, delete, and report on items.

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**Note:** Assign responsibilities to the GR\_ITEM\_GENERAL field name class to allow access to General Item Information on the Item Information navigator. Do not add or delete field names assigned to this field name class because this can cause unpredictable results on the Item Information navigator.

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### Defining Regulatory General Item Information for Existing Items Procedure

To enter general item information for existing items:

1. Navigate to the **Find Regulatory Items** window.
2. Perform one of the following:
  - Enter a full or partial item name and click **Find**. All items that match your criteria displays.
  - Enter a specific item name.
3. Select the item to view or edit general information for.
4. Click **Regulatory Item Detail**. The Regulatory Information window displays.
5. Click **General Item Information** to complete, view, or edit this information.
6. Save the window.

### General Item Information for Existing Items Field Reference

The fields on this window are:

#### **Primary CAS Number**

Enter the CAS (Chemical Abstracts Service Chemical Registry System) Number. The American Chemical Society's Chemical Abstract Service assigns CAS numbers.

The format for CAS numbers is XXXXXX-XX-X. While the format example shows the maximum number of digits for a CAS number, the first section of the number can be from a minimum of 2 digits to a maximum of 6 digits.

### **Regulatory Item Creator**

Enter the item creator. Defaults to the user name that you are logged in as. Required.

### **Product Class**

If the item is a member of a product class, then enter that product class code. Field names excluded from that product class are not displayed on the Item Information navigator.

### **Item Group Code**

If the item is a member of an item group, enter that item group code.

### **Internal Reference Number**

Enter a unique reference number to display on the document for the item. Informational only.

### **Product Label Code**

For future use.

### **Item Version**

Enter the revision number of the item to reflect that changes have been made.

### **Previous Item Version**

Displays the prior revision number of the item before the latest changes were made.

### **Actual Hazard**

Available when the Ingredient check box is selected and the Explode Ingredients check box is cleared. Unavailable when both Ingredient and Explode Ingredients are selected or both are cleared.

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**Caution:** The ingredient is reduced based on this percentage for components that are not 100% hazardous.

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Enter the percentage of the item that is hazardous. The default is 100% when you select the Explode Ingredient check box to break the ingredient into its components. To calculate the percentage from OPM Regulatory Management or OPM Product Development, leave the actual hazard percentage at 100. Required.

### **Ingredient Flag**

- Clear if the item is a product. Default.
- Select if this item is an ingredient at its lowest level in the formula.

### **Explode Ingredient Flag**

Available when the ingredient flag is selected.

- Clear if the ingredient is at its lowest level in the formula. Default.
- Select to explode the ingredient into its components.

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**Note:** A formula must exist in either the Formulator or Regulatory Management applications for any ingredient that you plan to explode.

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### **Formula Source Indicator**

Select the application where the formula explosion information is located for the ingredient or product. This formula is used for reporting 100% of the substances that make up the ingredient or product in MSDS Section 2. Required.

- **Formula.** An item that contains a formula in Product Development that can be broken down into components.
- **Stand Alone.** An item in only Regulatory Management that can be broken down into components.
- **No Formula.** An ingredient at its lowest level, whether it is part of a formula or a standalone item.

Formulas are exploded based on the recipes and validity rules associated with them. When Production Formula is selected as the Formula Source Indicator, components are exploded based on the existing active Regulatory or Product Development recipe and validity rules or both. The validity rule precedence is:

1. Regulatory validity rule for the default organization
2. Regulatory validity rule with no organization specified
3. Production validity rule for the default organization
4. Production validity rule with no organization specified

The organization specified in the validity rule must match the organization specified in the GR: Default Organization Code profile option.

See: *Oracle Process Manufacturing Product Development User's Guide*

**[ ]**

The double brackets ( [ ] ) identify a descriptive flexfield that you can use to add data fields to this window without programming. This descriptive flexfield lets you add your own information to the item.

## Defining Regulatory Item Detail Information

Use the Regulatory Information window to define and maintain hazard information for items in Regulatory Management.

### Defining Regulatory Item Detail Information Procedure

To enter item detail information:

1. Click **Regulatory Item Detail** from the Find Regulatory Items window. The Regulatory Information window displays.
2. Complete, view, or edit the information for each node on the Item Information navigator as described.
3. Save the window.

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**Note:** If you make any changes while on the Item Information navigator window, the system prompts you to reset the rebuild indicator.

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### Multilingual Descriptions Field Reference

Multilingual Descriptions lets you enter the following in each language for which you are creating documents:

- Chemical Family
- MSDS Name
- Shipping Name
- Trade Name

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**Note:** Assign responsibilities to the NAMES field name class which uses the Names form block to allow access to Multilingual Descriptions on the Item Information navigator. You can add or delete field names for this field name class.

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The fields on this window are:

**Language**

Enter a valid language description. Enter every language that you are creating documents for. Required.

**Description**

Enter the multilingual name in the language selected. Enter the name in every language that you are creating documents in. Required.

## European Data Field Reference

European Data lets you enter standard European risk, safety, and hazard information for items. European Hazard Classifications calculates product information based on the combined ingredient information that comprises it. Ingredients that comprise a product can be any combination of those entered on European Data.

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**Note:** Assign responsibilities to the GR\_EUROPE field name class which uses the Europe form block to allow access to European Data on the Item Information navigator. You can add field names to this field name class for tracking information. Do not add or delete field names assigned to this field class because it can cause unpredictable results on the Item Information navigator.

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### **To classify hazard, risk, and safety data on the European Data window:**

Complete the European Information: Hazard Classification, Risk Phrases, and Safety Phrases regions as required for the ingredients that comprise the product that you want to classify.

## European Information

The fields on this window are:

### **European Index Number**

Enter the European Index Number (XXX-XXX-XX-X format) for the item. Enter up to 12 characters including dashes.

### **EEC Number**

Enter the European Economic Community [EINECS (XXX-XXX-XX-X format) or ELINCS (XXX-XXX-X format)] number for the item. Enter up to 12 characters including dashes.

### **Consolidated Risk Phrase**

Displays all risk phrases that apply to the item. Each risk phrase that you select is automatically separated by a dash. For example, R14, Reacts violently with water and R15, Contact with water liberates extremely flammable gases displays as the consolidated risk phrase R14-15. Combination risk phrases are separated by a slash

(/). For example, R14/15, displays the combination risk phrase, Reacts violently with water, liberating extremely flammable gases.

### **Consolidated Safety Phrase**

Displays all safety phrases that apply to the item. Each safety phrase that you select is automatically separated by a dash. For example, S1, Keep locked up and S2, Keep out of the reach of children displays as the consolidated safety phrase S1-2. Combination safety phrases are separated by a slash (/). For example, S1/2, displays the combination safety phrase, Keep locked up and out of the reach of children.

## **Hazard Classification**

### **Code**

Enter the European hazard classification code.

### **Description**

Displays automatically when the hazard classification code is entered.

## **Risk Phrases**

### **Code**

Enter the risk phrase code. Enter as many risk phrase codes as necessary.

### **Phrase Code**

If additional phrase information is required for the selected risk phrase, then this field is available.

### **Temperature**

If additional temperature information is required for the selected risk phrase, then this field is available. Enter the temperature.

### **Scale**

If additional temperature information is required for the selected risk phrase, then this field is available, and select the scale. Scale defaults from the value on the GR: Default Temperature Calculation profile option. Example scales include:

- Celsius

- Fahrenheit
- Kelvin

## **Safety Phrases**

### **Code**

Enter the safety phrase code. Enter as many safety phrase codes as necessary.

### **Phrase Code**

If additional phrase information is required for the selected safety phrase, then this field is available. Enter the phrase code.

### **Temperature**

If additional temperature information is required for the selected safety phrase, then this field is available. Enter the temperature.

### **Scale**

If additional temperature information is required for the selected safety phrase, then this field is available, and select the scale. Scale defaults from the value on the GR: Default Temperature Calculation profile option. Example scales include:

- Celsius
- Fahrenheit
- Kelvin

## Exploded Components Field Reference

Exploded components lets you explode items into components based on formulas, recipes, and validity rules or enter the components of standalone items entered in Regulatory Management.

An item must already exist in OPM Regulatory Management before you can enter it as an ingredient item code.

Add new items or edit formula source indicators on the General Item Information window.

Assign responsibilities to the GR\_EXPLOSION field name class and Europe form block to allow access to Exploded Components Information on the Item Information navigator. You can add field names to this field name class for tracking information. Do not add or delete field names assigned to this field class because it can cause unpredictable results on the Item Information navigator.

Proper access to a formula is defined through Formula Security Profiles. Access to a formula can be defined as view only or view and update.

See: *Oracle Process Manufacturing Product Development User's Guide*

The fields on this window are:

### Ingredient Item Code

- Enabled if the formula source indicator on the General Item Information window is set to Stand Alone. Enter a valid ingredient item code. Enter all ingredients in the OPM Regulatory Management item. Required.
- Disabled if the Formula Source Indicator on the General Item Information window is set to Formula. The formula is exploded in the respective OPM application and displays here.
- Disabled if the Formula Source Indicator on the General Item Information window is set to No Formula. The item displays at 100%.

### Percent

- Enabled if the Formula Source indicator on the General Item Information window is set to Stand Alone. Enter a valid ingredient percentage. Enter percentages for all ingredients listed for the OPM Regulatory Management item. Required.

- Disabled if the Formula Source indicator on the General Item Information window is set to Formula. The percentage for each ingredient in the formula is exploded in the respective OPM application and displayed here.
- Disabled if the Formula Source indicator on the General Item Information window is set to No Formula. The item displays at 100%.

### **Refresh Formula Explosion**

Available if the Formula Source indicator on the General Item Information window is set to Formula. Click to update the display to reflect the most current item explosion information from the Formulator application.

## Item Information Navigator Reference

When you click Regulatory Item Detail from the Find Regulatory Items window, the selected item displays. Use the Item Information navigator to enter item data. The field name classes, field names, and properties that you set up display on the navigator. Only field name classes that are assigned to your field name class responsibility are visible. And only field names without exclusions for the displayed product class are visible. Edit field name classes, field names, and properties in Setup; you cannot edit them on the navigator.

The Find option locates text in the open items on the Item Information navigator. Use the percent (%) wildcard to represent any number of characters and the underline ( ) wildcard to represent any single character in your search. For example, search for %PHYSICAL% to locate the physical properties for the item. If you are not using the %, then you must type the full text that you want to find in the same case that it is displayed in.

See: *Oracle Applications User's Guide*

Following are the options available on the Actions menu and toolbar:

### **Open Item**

Opens an item. Select the item to display on the Item Information navigator. Multiple items can be open at once.

### **Close Item**

Closes the selected item.

### **Copy Item**

Copies an item and all its associated records. After selecting Copy Item, Paste Item is enabled.

### **Paste Item**

Displays the Paste Item Details window. Enter the new item code that contains the item that you copied and all of its associated records.

### **Expand**

Expands the currently selected item, field name class, or field name.

**Collapse**

Collapses the currently selected item, field name class, or field name.

**Expand All**

Expands all open items, field name classes, and field names.

**Collapse All**

Collapses all open items, field name classes, and field names.

**E-record Details**

Opens the E-records Detail window and lets you search on the E-record detail.

## Defining Master Item Associations

Use the Master Item Associations window to define and maintain the inventory item links to master regulatory items. You can add, edit, delete, and report on master item associations.

### Defining Master Item Associations Procedure

To enter master item associations:

1. Navigate to the **Master Item Associations** window.
2. Complete the fields as described.
3. Perform one of the following:
  - If **Use Regulatory Item Description** is selected, then go to step 6.
  - If **Use Regulatory Item Description** is cleared, then go to step 4.
4. Select **Item Descriptions** from the **Actions** menu.
5. Complete the fields as described.
6. Click **OK**.
7. Save the window

You can use Attachments with this window. Refer to the *Oracle Applications User's Guide* for detailed information on using attachments and folders.

### Regulatory Master Item Associations Field Reference

The fields on this window are:

#### Master Item Associations

##### Master Regulatory Item

Select the item code that identifies the item defined in Regulatory. Required.

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**Note:** You can only select existing Regulatory Management Items on the Master Item Associations window. Define items in Regulatory Information on the General Item Information window.

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### **Description**

Displays the description for the master regulatory item.

## **Inventory Items**

### **Item**

Enter the inventory item from the OPM Inventory Management Item Master that you want to associate with the master regulatory item. Required.

### **Description**

Displays the description of the inventory item.

### **Use Regulatory Item Description**

- Select to display the master regulatory item description for the selected item.
- Clear to display the inventory item description that you enter for the selected item.

### **[ ]**

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming. This descriptive flexfield lets you add your own information to the master regulatory item.

## Item Descriptions Field Reference

The fields on this window are:

### **Language**

Enter a valid language. Enter every language that you are creating documents for. Required.

### **Description**

Enter an item description in the language selected in the Language field. Required.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming. This descriptive flexfield lets you add your own information to the master regulatory item.



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## Setting Up Regulatory Management

These topics explain setting up OPM Regulatory Management for reporting product hazard information based on your particular requirements. OPM Regulatory Management lets you manage information to describe qualities and hazards in all supported languages.

The following topics are covered:

- [Defining Product Classes](#)
- [Defining Disclosure Codes](#)
- [Defining Properties](#)
- [Defining Field Name Classes](#)
- [Defining Field Names](#)
- [Editing Field Name Class Assignments](#)
- [Defining European Index Numbers](#)
- [Defining Hazard Groups](#)
- [Defining Hazard Classifications](#)
- [Defining Risk Phrases](#)
- [Defining Safety Phrases](#)
- [Defining Item Group Codes](#)

## Defining Product Classes

Use the Product Classes window to define and maintain logical groupings for items with similar requirements or properties. You can then link these groupings to the appropriate field names on each Field Name Product Class Exclusions window, and items on the General Item Information window. Product classes let you exclude unnecessary field names from items within the specified product classes. You can add, edit, delete, and report on product classes.

### Defining Product Classes Procedure

To enter product classes:

1. Navigate to the **Product Classes** window.
2. Complete the fields as described.
3. Save the window.

### Product Classes Field Reference

The fields on this window are:

#### **Code**

Enter the code that identifies the product class. Required.

#### **Description**

Enter the description for the product class. Required.

## Defining Disclosure Codes

Use the Disclosure Codes window to define and maintain logical groupings for items with similar legislative or recipient reporting levels. You can then link these groupings to the appropriate recipients, items, or both. You can add, edit, delete, and report on disclosure codes

### Defining Disclosure Codes Procedure

To enter disclosure codes:

1. Navigate to the **Disclosure Codes** window.
2. Complete the fields as described.
3. Save the window.

### Disclosure Codes Field Reference

The fields on this window are:

#### **Code**

Enter the disclosure code that identifies the ingredient exposure reporting levels. Required.

#### **Description**

Enter the description for the disclosure code. Required.

## Defining Properties

Use the Properties window to define property IDs and their associated types, descriptions, and values. You can then link these properties to the appropriate field names.

Properties assist in field name maintenance by letting you modify language translations, information, and values as necessary. A basic set of properties is seeded into Regulatory Management. You can add, edit, delete, and report on property IDs and information. Enter properties in every language required on your documents. You must enter properties in your base language and all installed languages. Other languages are optional.

In addition, properties determine the data entry fields that display for each field name on the Item Information navigator. Define properties and assign them to field names before those properties display for the field names on the Item Information navigator.

The following shows the flow of information on the Item Information navigator:

### Item Information

- Field Name Classes (primary node). For example, Physical Data
  - Field Name (secondary node). For example, Boiling Range
- Properties (data entry window). For example, Low Number, High Number, and Scale. Once properties are defined, enter data, such as 200 - 215 Fahrenheit on the properties window.

### Prerequisite

Define languages before defining properties.

See: *Oracle Applications User's Guide*

## Defining Properties Procedure

To enter properties:

1. Navigate to the **Properties** window.
2. Complete the fields as described.
3. Save the window.

## Properties Field Reference

The fields on this window are:

### Properties

#### **Property ID**

Enter a property ID. Required.

#### **Property Type**

Select a property type. Required.

- Flag
- Numeric
- Alphanumeric
- Date
- Phrase

#### **Length**

Enter the field length for the property.

#### **Precision**

Enter the decimal precision of the field if the property type is numeric.

#### **Range Min**

Enter the minimum value for the range if the property type is numeric.

#### **Range Max**

Enter the maximum value for the range if the property type is numeric.

### Details

#### **Language**

Select the language that the property description displays. Base and installed languages required.

### **Property Description**

Enter the property description in the selected language. The description displays on the data entry window for the field names that this property is linked to. Required.

## **Values**

### **Display Order**

Enter the display order for the value if the property type is flag. Required.

### **Value**

Enter the value code for the value if the property type is flag. Required.

### **Value Description**

Enter the value description in the selected language if the property type is flag.

## Defining Field Name Classes

Use the Field Name Classes window to define and maintain the logical groupings of field names that pertain to similar information. You can then link field name classes to the appropriate field names. A basic set of field name classes and field names are seeded into Regulatory Management. You can add, edit, delete, and report on field name classes. Enter field name classes in your base language and all installed languages. Other languages are optional.

In addition, field name classes and field name class responsibilities determine the primary categories of item information that display on the Item Information navigator. Define field name classes and assign their responsibilities before those field name classes display on the Item Information navigator. All field names assigned to the field name classes that you have field name class responsibilities for display under those field name classes on the Item Information navigator.

Field Name class responsibilities provide security options for accessing information. You can omit field name classes from group or individual responsibilities to prevent sensitive information from being available to those responsibilities. You can also limit the access that group and individual responsibilities have to a specific field name class by selecting the Allow Create Update check box. Clearing this check box allows query-only access.

The following shows the flow of information on the Item Information navigator:

### **Item Information**

- Field Name Classes (primary node). For example, Physical Data

Field Name (secondary node). For example, Boiling Range

Properties (data entry window for secondary node). For example, Low Number, High Number, and Scale. Once properties are defined, you can then enter data, such as 200 - 215 Fahrenheit on the properties window.

### **Prerequisite**

Define languages before defining field name classes.

See: *Oracle Applications User's Guide*

## Defining Field Name Classes Procedure

To enter field name classes:

1. Navigate to the **Field Name Classes** window.
2. Complete the fields as described.
3. Click Field Name Class Responsibilities to access the **Field Name Class Responsibilities** window and add responsibilities for the field name class.
4. Complete the fields as described.
5. Save the window.

## Field Name Classes Field Reference

The fields on this window are:

### Field Name Classes

#### Field Name Class

Enter the code that identifies the field name class. Required.

#### Form Block

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**Note:** Unless you are creating a new node in the Item Information navigator, leave this field alone. Some field name classes have no form block assigned to them.

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If you are creating a node for a field name class in the Item Information navigator, enter the form block name. The form block determines which data entry window displays for field names in the specified field name class.

When these field names are attached to document structures, the data you entered on the form block is the data that displays in printed documents. Valid values are:

- Properties - This form block is used for the following field name classes: Physical Data, Heavy Elements, Transportation, and Additional Item Information. The Properties form block lets you enter values such as boiling and flash ranges; heavy element concentrations in parts per million; chemical identification numbers for transport. In addition, you can modify the Properties form block for each field name by adding or deleting properties.

- **Item General** - This form block is used for the General Item Information field name class. The Item General form block lets you enter information such as primary CAS Number, Document Author, Product Class, item versions, and formula source information.
- **Names** - This form block is used for the Multilingual Descriptions field name class. The Names form block lets you enter Chemical Family, MSDS, Shipping and Trade Names for items in every language.
- **Europe** - This form block is used for the European Data field name class. The Europe form block lets you enter hazard classifications, risk phrases, and safety phrases for non-Approved Supply List items and to classify products based on any combination of ASL or non-ASL ingredients.
- **Explosion** - This form block is used for the Exploded Components field name class. The Explosion form block lets you enter or calculate the ingredients and their concentration percentages for items based on their formula source.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data field names to this window without programming. This descriptive flexfield lets you add your own information to the field name class.

## Details

### Language Description

Enter a valid language description. Base and installed languages required.

### Field Name Class Description

Enter the description for the field name class in the selected language. The field name class description that you enter displays as a primary node on the Item Information navigator. Required.

## Field Name Class Responsibilities Field Reference

The fields on this window are:

### **Responsibility**

Enter the name of the responsibility that has security access to the field name class. The field name class is then accessible to the person with this responsibility on the Item Information navigator.

### **Display Sequence**

Enter the sequence that the field name class displays in on the Item Information navigator. For example, a field name class with a display sequence of 10 displays after one with a sequence of 5.

### **Create**

Select to allow the responsibility query and write access to the field name class. You can then create and update information that is linked to the field names within the specific field name class on the Item Information navigator. Default.

### **Query**

Select to allow the responsibility query-only access to the field name class. You can then only view information that is linked to the field names within the specific field name class on the Item Information navigator.

### **Field Name Class Assignments**

Click Field Name Class Assignments to display and edit the field name classes that are assigned to a responsibility and their associated sequences for display on the Item Information navigator.

## Defining Field Names

Use the Field Names window to define and maintain the field names.

A basic set of field names is seeded into Regulatory Management. You can add, edit, delete, and report on field names. You can enter field names in every language. Enter field names in your base language and all installed languages. Other languages are optional.

In addition, field names determine the secondary categories of item information that display on the Item Information navigator. Define field names and assign them to field name classes before those field names display for the field name classes on the Item Information navigator.

The following shows the flow of information on the Item Information navigator:

### Item Information

- Field Name Classes (primary node). For example, Physical Data
  - Field Name (secondary node). For example, Boiling Range
    - Properties (data entry window for secondary node). For example, Low Number, High Number, and Scale. Once properties are defined, you can then enter data, such as 200 - 215 Fahrenheit on the Properties window.

### Prerequisites

Define properties before defining field names.

Define languages before defining field names.

See: *Oracle Applications User's Guide*

## Defining Field Names Procedure

The field names are a grouping of properties used to capture data against an item.

To enter field names:

1. Navigate to the **Field Names** window.
2. Complete the fields as described.
3. If you want to exclude field names from one or more product classes, then click **Product Classes** to access the **Field Name Product Class Exclusions** window.
4. Enter the **Product Classes** that you want the field name to be excluded from.
5. Click **OK** to accept the Product Class exclusions and to navigate back to the **Field Names** window.
6. Save the window.

## Field Names Field Reference

The fields on this window are:

### Field Name Code

When you create heading field names for ingredients, they do not display on the navigator. You can create a field name class with no responsibilities assigned to it and assign all heading field names to that field name class.

Enter the 5-character numeric code that identifies the field name. This is user-definable.

### Field Name Class

Select a field name class from the list. The field name displays under this field name class on the Item Information navigator. Required.

### Safety

Enter the safety category. The safety category identifies the type of safety phrase that is applied for European hazard classifications. For example, when Consumer Use is the selected safety category, the safety phrase "Keep out of reach of children" is applied. The default safety category is "Not used." Required.

### Technical Parameter

You can retrieve information from laboratory technical parameters.

- Select to retrieve item property information from technical parameters.
- Clear to avoid retrieving item property information from technical parameters.

To retrieve technical parameter data, create field names. The field name descriptions must match the Technical Parameter Names identically, including case. The appropriate properties are retrieved on the Field Names window and displayed on the Item Information navigator, along with the data from Item Technical Data and, if the technical parameter is linked to a quality control assay, from quality control specifications. Only global quality control assays, those which have no organizations assigned, are retrieved by OPM Regulatory Management.

Following are the property values that are retrieved into Regulatory Management:

- The Character data type displays VALUE, HI\_CHAR, LW\_CHAR, and UNIT properties.
- The Numeric data type displays VALUE, HIGH, LOW, and UNIT properties.

- The Boolean data type displays the VALUE.
- Seeded properties to use with the technical parameter data:
- HI\_CHAR - The last allowable character in the range, such as Z.
  - LW\_CHAR - The first allowable character in the range, such as A.
  - HIGH - The last allowable number in the range, such as 500.
  - LOW - The first allowable number in the range, such as 0.
  - VALUE - The actual character or numeric value, such as RED or 212.
  - UNIT - The unit of measure for the value, such as Fahrenheit or Milliliter.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming. This descriptive flexfield lets you add your own information to the field name.

### **Language Description**

Enter a valid language description. Base and installed languages required.

### **Field Name Description**

Enter a field name description in the language selected in the language description. The field name description that you enter displays as a secondary node on the Item Information navigator.

If you are entering a heading field name for ingredient information, then the description displays as the heading field name in place of the original field name. Required.

### **Property ID**

Enter a valid property ID for the field name. Property information is not used for ingredient names. They use properties from the base field name. Required.

### **Required**

- Select to make the specified property required on the Regulatory Item Information navigator. For example, for the field name Boiling Range, you can select Required for high number, low number, and scale. Then, those are required fields during data entry.

- Clear to make the specified property not required. Default.

**Property Type**

Displays the property type associated with the selected property.

**Length**

Displays the length associated with the selected property.

**Precision**

If applicable, displays the decimal precision associated with the selected property.

**Range Min**

If applicable, displays the minimum value associated with the selected property.

**Range Max**

If applicable, displays the maximum value associated with the selected property.

## Excluding Field Names from Product Classes Procedure

You can exclude a field name from one or more Product Classes. Entering a product class on the Field Name Product Class Exclusions window excludes the specified field name from being displayed on the Item Information navigator for any Items within the specified product classes. The entry also prevents the field name from printing on item documents.

## Field Name Product Class Exclusions Field Reference

**Product Class**

Enter as many product classes as you want to exclude from the field name.

## Editing Field Name Class Assignments

Use the Field Name Class Assignments window to display and edit all field name classes assigned to a responsibility and the associated sequence number for display on the navigator.

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**Note:** Field Name Class Assignments can also be viewed and edited from the Field Name Class Responsibilities window.

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### Prerequisite

Define field name classes.

Define responsibilities.

See: *Oracle Applications User's Guide*

## Editing Field Name Class Assignments Procedure

To enter field name class assignments:

1. Navigate to the **Field Name Class Assignments** window.
2. Complete the fields as described.
3. Save the window.

## Field Name Class Assignments Field Reference

The fields on this window are:

### Responsibility Name

Enter the name of the responsibility that you want to view field name class assignments for.

### Description

Displays the description for the selected responsibility.

### Field Name Class

Displays all the field name classes assigned to the responsibility.

### **Field Name Class Description**

Displays the description associated with the field name class. The field name class descriptions display as the primary nodes on the Item Information navigator.

### **Display Order**

Displays the sequence that the field name class is displayed in on the Item Information navigator. For example, a field name class with a display sequence of 10 displays after one with a sequence of 5.

### **Create**

Select to allow the responsibility query and write access to the field name class. You can then create and update information that is linked to the field names within the specific field name class on the Item Information navigator. Default.

### **Query**

Select to allow the responsibility query-only access to the field name class. You can then only view information that is linked to the field names within the specific field name class on the Item Information navigator.

### **Resequence Display Order**

Click the up and down arrows to move the selected sequence in the display order. Save your changes, then click Resequence Display Order to resequence the field name classes so all of the numbers are in sequence.

For example, if you move 20 in the current display, which is Multilingual Descriptions, down to 30, then Physical Data is sequenced, and Multilingual Descriptions displays after Physical Data both on the Field Name Class Assignments window and on the Item Information navigator.

## Defining European Index Numbers

Use the European Index Numbers window to define and maintain items. You can enter items by their European Index Numbers with their associated hazard classification information. You can then link this information to items in European Information in the Item Information navigator to classify products based on their ingredient hazard information.

You can add, edit, and delete European Index Numbers information.

### Defining European Index Numbers Procedure

To define a European Index Number:

1. Navigate to the **European Index Numbers** window.
2. Complete the fields in each region as described.
3. Save the window.

### European Index Numbers Field Reference

The fields on this window are:

#### EIN Numbers

##### **European Index Number**

Enter a new or an existing European Index number. You can enter up to 12 characters including dashes. Required.

##### **EEC Number**

Enter the European Economic Community [EINECS (XXX-XXX-XX-X format) or ELINCS (XXX-XXX-X format)] number for the item. You can enter up to 12 characters including dashes.

##### **Chemical Formula**

Enter the Chemical Formula.

## Details

### Language Description

Enter a valid language description. Base and installed languages required.

### Chemical Description

Enter the description for the chemical in the selected language. Required.

## Hazard Classifications

Use this region to enter European hazard classifications for items whose classification remains static regardless of concentration limits.

### Code

Enter the European hazard classification code.

### Description

Displays the hazard classification description for the code being entered.

## Risk Phrases

### Code

Enter the risk phrase or combination code.

### Description

Displays the risk phrase description for the code being entered.

## Safety Phrases

### Code

Enter the safety phrase or combination code.

### Description

Displays the safety phrase description for the code being entered.

## Defining Hazard Groups

Use the Hazard Groups window to define and maintain logical groupings of hazard classifications with similar hazardous chemical properties. You can then link these groupings to the appropriate risk phrases.

Standard codes and descriptions are seeded into Regulatory Management. You can add, edit, delete, and report on hazard groups.

### Defining Hazard Groups Procedure

To enter hazard groups:

1. Navigate to the **Hazard Groups** window.
2. Complete the fields as described.
3. Save the window.

### Hazard Groups Field Reference

The fields on this window are:

#### **Code**

Enter the code that identifies the hazard group. Required.

#### **Description**

Enter the description for the hazard group. Required.

## Defining Hazard Classifications

Use the Hazard Classifications window to define and maintain hazard classifications required by European legislation to categorize the dangers of chemicals. Hazard classifications are required to ship chemicals within Europe or to ship them to Europe from other countries. You can link hazard classifications to items on the Regulatory Information window.

Hazard classifications let you maintain risk categories for items. Standard hazard classification codes and descriptions are seeded into Regulatory Management. You can add, edit, delete, and report on hazard classifications. Enter hazard classifications in your base language and all installed languages. Other languages are optional.

### Prerequisites

Define hazard group codes before defining hazard classifications.

Define languages before defining field names.

See: *Oracle Applications User's Guide*

## Defining Hazard Classifications Procedure

To enter hazard classifications:

1. Navigate to the **Hazard Classifications** window.
2. Complete the fields as described.
3. Save the window.

## Hazard Classifications Field Reference

The fields on this window are:

### Classification Code

Enter the code that identifies the hazard classification. Required.

### Group Code

Enter a valid hazard group code. The group code description displays automatically. Required.

## Details

### **Language Description**

Enter a valid language description. Base and installed languages required.

### **Hazard Description**

Enter the description for the hazard classification in the selected language.  
Required.

## Defining Risk Phrases

Use the Risk Phrases window to define and maintain the risk phrases required by European legislation to communicate chemical hazard information. Risk phrases are required on labels when shipping hazardous products within Europe or when shipping them to Europe from other countries. You can link risk phrases to items on the Regulatory Information window.

Standard codes and descriptions are seeded into Regulatory Management. You can add, edit, delete, and report on risk phrases. You can enter risk phrases in every language required on your documents. Enter risk phrases in your base language and all installed languages. Other languages are optional.

### Prerequisite

Define languages before defining risk phrases.

See: *Oracle Applications User's Guide*

## Defining Risk Phrases Procedure

To enter risk phrases:

1. Navigate to the **Risk Phrases** window.
2. Complete the fields as described.
3. Save the window.

## Risk Phrases Field Reference

The fields on this window are:

### Code

Enter a risk phrase code or combination. Required.

### Additional Information

Indicate whether additional information is required at the item level when the current phrase is used. Select one of the following:

- None - to indicate that no additional information is required. Default.
- Temperature
- Phrase

You can enter the specified additional information for risk phrases as phrases on the Phrase Library window. Select the additional risk phrase information in European Data on the Item Information navigator. Required.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming. This descriptive flexfield lets you add your own information to the Risk Phrases block.

## Details

### Language Description

Enter a valid language description. Base and installed languages required.

### Phrase Description

Enter the description for the phrase in the selected language.

When either Temperature or Phrase is selected in the Additional Information field, enter three consecutive periods (...) in the Phrase Description to indicate where the additional information must be inserted when the phrase is printed on documents.

For example, if you enter “Children” as additional information, and use a “Keep Away From...” “Risk Phrase, then the phrase reads “Keep Away From Children”. Required.

## Defining Safety Phrases

Use the Safety Phrases window to define and maintain the safety phrases required by European legislation to communicate chemical advice information. Safety phrases are required on labels when shipping hazardous products within Europe or when shipping them to Europe from other countries. You can link safety phrases to items on the Regulatory Information window.

Standard codes and descriptions are seeded into Regulatory Management. You can add, edit, delete, and report on safety phrases. You can enter safety phrases in every language required on your documents. Enter safety phrases in your base language and all installed languages. Other languages are optional.

### Prerequisite

Define languages before defining safety phrases.

See: *Oracle Applications User's Guide*

## Defining Safety Phrases Procedure

To enter safety phrases:

1. Navigate to the **Safety Phrases** window.
2. Complete the fields as described.
3. Save the window.

## Safety Phrases Field Reference

The fields on this window are:

### Code

Enter a safety phrase code or combination. Required.

### Additional Information

Indicate whether additional information is required at the item level when the current phrase is used. Select one of the following:

- None - to indicate that no additional information is required. Default.
- Temperature
- Phrase

You can enter the specified additional information for risk phrases as phrases on the Phrase Library window. Select the additional risk phrase information in European Data on the Item Information navigator. Required.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming. This descriptive flexfield lets you add your own information to the Safety Phrases block.

## Descriptions

### Language Description

Enter a valid language description. Base and installed languages required.

### Phrase Description

Enter the description for the phrase in the selected language. Required.

When either Temperature or Phrase is selected in the Additional Information field, enter three consecutive periods (...) in the Phrase Description to indicate where the additional information must be inserted.

For example, if you enter “Children” as additional information, and use a “Keep Away From...” Safety Phrase, then the phrase reads “Keep Away From Children”. Required.

## Defining Item Group Codes

Use the Item Group Codes window to define and maintain logical groupings of items with similar chemical properties. You can then link these groupings to the appropriate items on the General Item Information window.

You can add, edit, delete, and report on item groups. You can enter item groups in every language required. Enter item groups in your base language and all installed languages. Other languages are optional.

### Prerequisite

Define languages before defining properties.

See: *Oracle Applications User's Guide*

## Defining Item Group Codes Procedure

To enter item group codes:

1. Navigate to the **Item Group Codes** window.
2. Complete the fields as described.
3. Save the window.

## Item Group Codes Field Reference

The fields on this window are:

### Item Group Code

Enter the code that identifies the item group. Required.

### Details

### Language Description

Enter a valid language description. Base and installed languages required.

### Description

Enter the item group code description in the selected language. Required.

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## Running Regulatory Management Reports

This topic describes the available OPM Regulatory Management reports. Reports are available through the application's Standard Report Submission window. Refer to the *Oracle Applications User's Guide* or the online help topics for detailed information on running reports.

The following reports are covered:

- [Disclosure Codes Report](#)
- [European Index Numbers Report](#)
- [Field Name Class Codes Report](#)
- [Field Name Codes Report](#)
- [Hazard Classification Codes Report](#)
- [Hazard Classification Group Codes Report](#)
- [Item Group Codes Report](#)
- [Master Item Associations Report](#)
- [Properties Report](#)
- [Product Class Codes Report](#)
- [Risk Phrases Report](#)
- [Safety Phrases Report](#)

## Disclosure Codes Report

Use the Disclosure Codes Report to view all the disclosure codes and their associated descriptions set up in OPM Regulatory Management.

### Submitting the Report

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Complete the other fields on the **Submit Request** window.
4. Click **Submit Request**.

## European Index Numbers Report

Use the European Index Numbers Report to view the European Index Numbers and their associated classification information by item.

The report displays all of the European index numbers and their associated products or ingredients, hazard classification codes, risk phrases and safety phrases.

### Submitting the Report

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Complete the fields as described in the **Selected Report Parameters** topic.
4. Click **OK**.
5. Complete the other fields on the **Submit Request** window.
6. Click **Submit Request**.

### Selected Report Parameters

The fields on this window are:

#### From European Index Numbers

Select the first European index number in the range that you want to display classifications for.

#### To European Index Numbers

Select the last European index number in the range that you want to display classifications for.

#### From Item Code Information

Enter the first item code in the range that you want to display classifications for.

#### To Item Code Information

Enter the last item code in the range that you want to display classifications for.

## Field Name Class Codes Report

Use the Field Name Class Codes Report to view the field name class codes that are set up in OPM Regulatory Management.

The report displays the field name class codes in the language range selected along with their associated descriptions.

### Submitting the Report

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Complete the fields as described in the **Selected Report Parameters** topic.
4. Click **OK**.
5. Complete the other fields on the **Submit Request** window.
6. Click **Submit Request**.

### Selected Report Parameters

The fields on this window are:

#### From Language

Select the first language code in the range that you want to display field name class codes for. Field name class codes display in every language in the range.

#### To Language

Select the last language code in the range that you want to display field name class codes for. Field name class codes display in every language in the range.

## Field Name Codes Report

Use the Field Name Codes Report to view the field name codes that are set up in OPM Regulatory Management.

The report displays either the field name codes or field name class codes for the range and language range selected along with their associated descriptions.

### Submitting the Report

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Complete the fields as described in the **Selected Report Parameters** topic.
4. Click **OK**.
5. Complete the other fields on the **Submit Request** window.
6. Click **Submit Request**.

### Selected Report Parameters

The fields on this window are:

#### Print Report For

Select to print the report by field name class code or field name code.

#### From Field Name Class

If you have selected to print the report by field name class, select the first field name class code in the range that you want to display field name class codes for.

#### To Field Name Class

If you have selected to print the report by field name class, select the last field name class code in the range that you want to display field name class codes for.

#### From Field Name

If you have selected to print the report by field name, select the first field name code in the range that you want to display field name codes for.

**To Field Name**

If you have selected to print the report by field name, then select the last field name code in the range that you want to display field name codes for.

**From Language**

Select the first language code in the range that you want to display field name or field name class codes for. Codes display in every language in the range.

**To Language**

Select the last language code in the range that you want to display field name or field name class codes for. Codes display in every language in the range.

## Hazard Classification Codes Report

Use the Hazard Classification Codes Report to view the hazard classification codes that are set up in OPM Regulatory Management.

The report displays the hazard classification codes in the language range selected along with their associated group codes, descriptions, and language codes.

### Submitting the Report

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Complete the fields as described in the **Selected Report Parameters** topic.
4. Click **OK**.
5. Complete the other fields on the **Submit Request** window.
6. Click **Submit Request**.

### Selected Report Parameters

The fields on this window are:

#### From Language

Select the first language code in the range that you want to display hazard classification codes for. Hazard classification codes display in every language in the range.

#### To Language

Select the last language code in the range that you want to display hazard classification codes for. Hazard classification codes display in every language in the range.

## Hazard Classification Group Codes Report

Use the Hazard Classification Group Codes Report to view the hazard classification group codes that are set up in OPM Regulatory Management.

The report displays all of the hazard classification group codes and their descriptions.

### Submitting the Report

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Complete the other fields on the **Submit Request** window
4. Click **Submit Request**.

## Item Group Codes Report

Use the Item Group Codes Report to view the item group codes that are set up in OPM Regulatory Management.

The report displays all of the item group codes, their associated languages, and descriptions.

### Submitting the Report

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Complete the other fields on the **Submit Request** window.
4. Click **Submit Request**.

### Selected Report Parameters

The fields on this window are:

#### From Language

Select the first language code in the range that you want to display item group codes for. Item group codes display in every language in the range.

#### To Language

Select the last language code in the range that you want to display item group codes for. Item group codes display in every language in the range.

## Master Item Associations Report

Use the Master Item Associations Report to view the master item associations that are set up in OPM Regulatory Management.

The report displays master items in the range selected along with the inventory item codes that are linked to the master item and the description flag for the language.

If the description flag is set to no, then the associated language code and shipping item description display for the item. If the description flag is set to yes, then the associated language code and shipping item description do not display for the item.

### Submitting the Report

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Complete the other fields on the **Submit Request** window.
4. Click **Submit Request**.

### Selected Report Parameters

The fields on this window are:

#### From Master Regulatory Item

Select the first master regulatory item code in the range that you want to display master items with their linked inventory item information for.

#### To Master Regulatory Item

Select the last master regulatory item code in the range that you want to display master items with their linked inventory item information for.

## Properties Report

Use the Properties Report to view the properties that are set up in OPM Regulatory Management.

The report displays the property IDs with their associated type, length and precision, minimum and maximum range, language, and description.

### Submitting the Report

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Complete the other fields on the **Submit Request** window.
4. Click **Submit Request**.

### Selected Report Parameters

The fields on this window are:

#### From Property ID

Select the first property ID in the range that you want to display properties for.

#### To Property ID

Select the property ID in the range that you want to display properties for.

## Product Class Codes Report

Use the Product Class Codes Report to view the product class codes that are set up in OPM Regulatory Management.

The report displays product class codes with their associated descriptions and the auto assign safety phrase flag settings.

### Submitting the Report

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Complete the other fields on the **Submit Request** window.
4. Click **Submit Request**.

## Risk Phrases Report

Use the Risk Phrases Report to view the risk phrases that are set up in OPM Regulatory Management.

The report displays risk phrase codes with their associated languages and descriptions for the language range selected.

### Submitting the Report

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Complete the fields as described in the **Selected Report Parameters** topic
4. Click **OK**.
5. Complete the other fields on the **Submit Request** window.
6. Click **Submit Request**.

### Selected Report Parameters

The fields on this window are:

#### From Language

Select the first language code in the range that you want to display risk phrase information for. Codes display in every language in the range.

#### To Language

Select the last language code in the range that you want to display risk phrase information for. Codes display in every language in the range.

## Safety Phrases Report

Use the Safety Phrases Report to view the safety phrases that are set up in OPM Regulatory Management.

The report displays safety phrase codes with their associated languages and descriptions for the language range selected.

### Submitting the Report

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Complete the fields as described in the **Selected Report Parameters** topic.
4. Click **OK**.
5. Complete the other fields on the **Submit Request** window.
6. Click **Submit Request**.

### Selected Report Parameters

The fields on this window are:

#### From Language

Select the first language code in the range that you want to display safety phrase information for. Codes display in every language in the range.

#### To Language

Select the last language code in the range that you want to display safety phrase information for. Codes display in every language in the range.

# A

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## Appendixes

This topic explains typical navigation paths and specific profile options that need to be set up.

The following topics are covered:

- Navigation Paths
- Profile Options

## Navigation Paths

Although your System Administrator may have customized your navigator, typical navigation paths are described in the following table. In some cases, there is more than one way to navigate to a form. This table provides the most typical default path.

<b>Window</b>	<b>Path</b>
Additional Item Information	OPM Regulatory Document Management:Items:Regulatory Information:Find Regulatory Items:Regulatory Item Detail:Additional Item Information
Address (Recipients drill down)	OPM Regulatory Document Management:Setup:Recipient Information:Recipients:Actions:Address Edit
Configuration Variables	ERES Administrator:Setup:Configuration Variables
Disclosure Codes	OPM Regulatory Document Management:Setup:Disclosure Codes
Disclosure Codes Report	OPM Regulatory Document Management:Reports:Run
Edit Cover Letter Text	OPM Regulatory Document Management:Setup:Recipient Information:Cover Letters:Edit Text
Edit European Index Numbers	OPM Regulatory Document Management:Setup:European Information:European Index Numbers
Edit Phrase Text	OPM Regulatory Document Management:Setup:Phrases:Phrase Library:Actions:Edit Phrase Text
eRecord Generator	ERES Administrator:Utilities:eRecord Generator
European Data	OPM Regulatory Document Management:Items:Regulatory Information:Find Regulatory Items:Regulatory Item Detail:European Data
European Index Numbers	OPM Regulatory Document Management:Setup:European Information:European Index Numbers
European Index Numbers Report	OPM Regulatory Document Management:Reports:Run
Evidence Store - Administrator	ERES Administrator:Inquiry:Evidence Store

<b>Window</b>	<b>Path</b>
Evidence Store - User	ERES User:Inquiry:Evidence Store
Exploded Components	OPM Regulatory Document Management:Items:Regulatory Information:Find Regulatory Items:Regulatory Item Detail:Exploded Components
Field Name Class Assignments	OPM Regulatory Document Management:Field Names:Field Name Class Assignments
Field Name Class Codes Report	OPM Regulatory Document Management:Reports:Run
Field Name Class Responsibilities	OPM Regulatory Document Management:Setup:Field Names:Field Name Classes:Responsibilities
Field Name Classes	OPM Regulatory Document Management:Setup:Field Names:Field Name Classes
Field Name Codes Report	OPM Regulatory Document Management:Reports:Run
Field Name Product Class Exclusions	OPM Regulatory Document Management:Setup:Field Names:Field Names:Product Classes
Field Names	OPM Regulatory Document Management:Setup:Field Names:Field Names
Files Approval	iSign Administrator:Files Approval iSign User:Files Approval
Find Regulatory Items	OPM Regulatory Document Management:Items:Regulatory Information
General Item Information (Edit)	OPM Regulatory Document Management:Items:Regulatory Information:Find Regulatory Items:Regulatory Item Detail:General Item Information
General Item Information (New)	OPM Regulatory Document Management:Items:Regulatory Information:New:General Item Information
Hazard Classification Codes Report	OPM Regulatory Document Management:Reports:Run
Hazard Classification Group Codes Report	OPM Regulatory Document Management:Reports:Run
Hazard Classifications	OPM Regulatory Document Management:Setup:European Information:Hazard Classifications

<b>Window</b>	<b>Path</b>
Hazard Groups	OPM Regulatory Document Management:Setup:European Information:Hazard Groups
Item Group Codes	OPM Regulatory Document Management:Setup:Item Group Codes
Item Group Codes Report	OPM Regulatory Document Management:Reports:Run
Master Item Associations	OPM Regulatory Document Management:Items:Master Item Associations
Multilingual Descriptions	OPM Regulatory Document Management:Items:Regulatory Information:Find Regulatory Items:Regulatory Item Detail:Multilingual Descriptions
Physical Data	OPM Regulatory Document Management:Items:Regulatory Information:Find Regulatory Items:Regulatory Item Detail:Physical Data
Product Class Codes Report	OPM Regulatory Document Management:Reports:Run
Product Classes	OPM Regulatory Document Management:Setup:Product Classes
Profile Options	OPM Regulatory Document Management:Other:Profile Options
Properties	OPM Regulatory Document Management:Setup:Field Names:Properties
Properties Report	OPM Regulatory Document Management:Reports:Run
Regulatory Information	OPM Regulatory Document Management:Items:Regulatory Information:Find Regulatory Items:Regulatory Item Detail
Risk Phrases	OPM Regulatory Document Management:Setup:European Information:Risk Phrases
Risk Phrases Report	OPM Regulatory Document Management:Reports:Run
Safety Phrases	OPM Regulatory Document Management:Setup:European Information:Safety Phrases
Safety Phrases Report	OPM Regulatory Document Management:Reports:Run
Security Rules	ERES Administrator:Setup:Security Rules

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<b>Window</b>	<b>Path</b>
Session Parameters	OPM Regulatory Document Management:Other:Session Parameters
Update Completed Jobs	OPM Regulatory Document Management:Print from Order Fulfillment:Completed Print Jobs:Update
XML Elements	ERES Administrator:Setup:XML Elements
XML Generator	ERES Administrator:Utilities:XML Generator

## Profile Options

During your implementation, you set a value for selected profile options to specify how your Regulatory Management application controls access to and processes data. Regulatory Management uses the listed profile options:

See: *Oracle Process Manufacturing Implementation Guide*

- GR: Default Safety Category
- GR: Default Temperature Calculation
- GR: Document Management
- GR: File Exists Action

You can set up these profile options when you set up other applications prior to your Regulatory Management implementation. Refer to the other product user's guides for more details on how these products use these profile options.

Your System Administrator sets user profile options at one or more of the following levels: Site, Application, Responsibility, and User. Use the Personal Profile Options window to view or set your profile options at the user level. You can consult the *Oracle Process Manufacturing Implementation Guide* for a complete description of the profile options listed. Consult your *Oracle Applications System Administrator's Guide* for a list of profile options common to all Oracle Applications.

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# Glossary

## **ACGIH**

American Conference of Governmental Industrial Hygienists. US organization that establishes occupational exposure limits for substances.

## **Action Phrase**

Action phrases replace conflicting phrases with the same phrase type and hierarchy. For example, the phrases "Wash with soap and water" and "Do not wash with soap under any circumstances" can be replaced with a conflict action phrase such as "Rinse with water" that prints on documents when the conflict occurs.

## **ADN**

European regulations for the international transport of dangerous goods via inland waterways in the European states.

## **ADR**

European regulations for the international transport of dangerous goods via road in the European states.

## **ANSI**

American National Standards Institute.

## **Auto Ignition Point**

The temperature that a substance spontaneously ignites at.

## **Boiling Range/Point**

The temperature or range of temperatures that a liquid turns to vapor at.

**Carcinogen**

A substance that causes cancer.

**CAS**

Chemical Abstracts Service. Catalogs chemical substances.

**CAS Number**

The Chemical Abstracts Service numbers assigned to items.

**CEPA**

Canadian Environmental Protection Act. A Canadian environmental law that requires the domestic substances list (DSL) and the non-domestic substances list (NDSL).

**CERCLA**

Comprehensive Environmental Response, Compensation, and Liability Act. A US EPA law.

**CHEMTREC**

Chemical Transportation Emergency Center. Provides 24-hour transportation emergency information to registered companies.

**CONEG**

Conference of North Eastern Governors. Passed laws in several states that regulate the amount of lead, mercury, cadmium, and hexavalent chromium in packaging materials.

**Corrosive**

A substance that changes or destroys living tissue.

**COSHH**

Control of Substances Hazardous to Health. UK legislation.

**Density**

The mass per unit volume of a material.

**Disclosure Code**

Disclosure codes are groupings of legislative reporting levels linked to legislative or recipient requirements and their respective recipients.

**DOT**

Department of Transportation. A US government agency that regulates the transportation of hazardous materials.

**DSL**

Domestic Substances List. A Canadian list of items manufactured in or imported to Canada. The DSL is regulated by the CEPA.

**E-records**

Electronic Records.

**EEC**

European Economic Community.

**EH40**

In UK COSHH regulations, Guidance Note EH40 lists occupational exposure limits for substances in air.

**EHSC**

Environment, Health, and Safety Committee.

**EINECS**

European Inventory of Existing Chemical Substances. An EEC list of known chemical substances tracked by EINECS and CAS numbers.

**EINECS Number**

The number assigned to the items on the EINECS list.

**ELINCS**

European List of Notified Chemical Substances. Supplements the EINECS list.

**ELINCS Number**

The number assigned to the items in the ELINCS list.

**EPA**

Environmental Protection Agency. A US government agency that regulates and enforces environmental laws.

**ERG Number**

Emergency Response Guidebook Number. The item reference number in the ERG.

**Explosive**

A substance that releases pressure, gas, and heat suddenly when subjected to certain conditions.

**Explosive Limit**

The concentration range in percent of a gas or vapor that can explode.

**Exposure Authority**

Exposure authorities are companies or legislative bodies that determine the item exposure limit reporting requirements.

**Exposure Type**

Exposure types are the kinds of exposures that must be reported such as long-term, short-term, minimum, and maximum.

**Flammable**

A substance that produces a flame when subjected to certain conditions.

**Flash Point**

The minimum temperature that a liquid is ignitable at.

**Freezing Point**

The temperature that a liquid begins to form crystals or solidify at.

**Hazard**

The dangerous properties of a substance.

**Hazard Classification**

Hazard classifications are required when shipping chemicals within Europe and when other countries ship products to Europe. For example, an item that causes severe burns to humans and kills aquatic life if disposed of in rivers would have the European hazard classifications of Very Corrosive and Dangerous to the Environment.

**Hazard Groups**

Hazard groups describe the types of dangers that European hazard classifications have. For example, an item with the European hazard classifications of Very Corrosive and Dangerous to the Environment is included in the Health-Toxic and Environmental hazard classification groups.

**HMIS**

Hazardous Material Information System. A US system of rating the health, flammability, and reactivity of substance hazards for workers. Substances in each hazard category are rated from 0-4.

**IARC**

International Agency for Research on Cancer. The IARC ranks actual and potential carcinogens.

**IATA Class**

International Air Transport Association classification.

**ICAO**

International Civil Aviation Organization.

**IMDG Class**

International Maritime Dangerous Goods classification.

**Irritant**

A substance that inflames living tissue, but does not irreversibly change or destroy it.

**Item Groups**

Item groups group items that are in the same chemical family or share the same properties such as organic acids. You can consolidate similar ingredients in a product into one item group on a document.

**Kemmler Code**

A European hazard identification number that is required on vehicles transporting dangerous goods in Europe.

**LC<sub>50</sub>**

Lethal Concentration Fifty. The calculated concentration of a substance in air that kills 50% of the test group with a single exposure.

**LC<sub>LO</sub>**

Lethal Concentration Low. The lowest concentration of a substance in air that has caused death in humans or animals (except LC<sub>50</sub>.) The reported concentrations can be entered for periods of exposure less than (acute) or greater than (sub-acute and chronic) 24 hours.

**LD<sub>50</sub>**

Lethal Dose Fifty. The calculated amount of a substance that kills 50% of the test group with a single dose.

**LD<sub>LO</sub>**

Lethal Dose Low. The lowest dose of a substance introduced by a route other than inhalation, over a period of time, in one or more portions, that has caused death in humans or animals (except LD<sub>50</sub>).

**LTEL**

Long-term exposure limit.

**MEL**

Maximum exposure limit.

**Melting Point**

The temperature that a solid begins to liquefy at.

**MFAG Table Number**

The Medical First Aid Guide reference numbers for items.

**MITI Number**

Japanese Ministry of International Trade and Industry number for the item.

**MSDS**

Material Safety Data Sheets are documents that provide information about hazardous materials. OSHA regulation 29 CFR Part 1910.2000, European Directive 91/155/EEC, and Canadian Regulations exist for MSDS documents.

**Mutagen**

A substance that alters the genetic makeup of a cell.

**NDSL**

Non-domestic Substances List. Lists items that are not part of the Canadian market and are considered non-domestic. The list is based on TSCA.

**Neoplastigen**

A substance that causes benign or malignant growths.

**NFPA**

National Fire Prevention Association. Promotes fire protection and prevention.

**NPRI List**

National Pollution Regulatory Initiative. The NPRI list provides Canadian Regulatory legislation.

**Odor Threshold**

The lowest concentration of a substance detectable by smell.

**OSHA**

Occupational Safety and Health Administration. A US government agency that regulates workplace safety and publishes the Hazard Communication Standard for document and labeling requirements.

**Oxidizer**

A substance that causes combustion in other materials.

**Partition Coefficient**

The distribution of a substance or mixture between two phases, such as between a liquid and a gas.

**PEL**

Permissible Exposure Limit. A workplace concentration exposure limit.

**pH**

The concentration of hydrogen in a solution. The number, ranging from 0 - 14 describes the degree of acidity (0 - 7) or alkalinity (7 - 14) of the solution.

**Phrase Code**

Phrase codes hold information about a product's dangers and qualities. For example, "Wash with Soap and Water."

**PIN Number**

Product Identification Number. A Canadian identification number that typically uses UN or NA numbers.

**Polymerization**

A chemical reaction that causes molecules to bond and form larger molecules. Polymerization is dangerous when the reaction releases large amounts of energy.

**Product Class**

Product classes are groupings of products with similar requirements or properties. For example, Liquids.

**Property ID**

Property IDs identify the different properties that are assigned to a label. For example, the boiling point label is associated with a temperature property ID. In addition, properties are set up on the Properties window and displayed on the window associated with each label on the Regulatory Information navigator.

**Property Type**

Property types identify the kinds of a property assigned to a label. For example, a property ID such as temperature can have a type of flag, numeric, alphanumeric, date, or phrase.

**Property Value**

Property values identify the valid values assigned to properties assigned the type flag. For example, the temperature property ID can have a list of valid temperature values such as Celsius, Fahrenheit, and Kelvin. The actual temperature is entered on the Regulatory Information navigator, on the property window associated with label.

**Proposition 65**

The Safe Drinking Water and Toxic Enforcement Act of 1986. Proposition 65 regulates warning requirements on materials that the US state of California has designated to be known carcinogens and/or teratogens.

**RID**

European regulations for the international transport of dangerous goods via rail in the European states.

**Right-to-Know Act**

A law requiring companies to supply product composition information on labels or documents or both. This law is also known as SARA Title III and is administered by the Environmental Protection Agency.

**Right-to-Know Labels**

The Right-to-Know Act requires companies to disclose the contents of materials by labeling containers with the ingredients.

**Risk**

A risk is the possibility that a substance's hazardous properties could cause harm to people or the environment.

**Risk Phrase**

Risk phrases supply information about the hazards of a chemical during normal use. Both European hazard classifications and risk phrases are required by EEC directives for chemical transport in Europe.

**Safety Phrase**

Safety phrases supply advice on safety precautions that are appropriate when using the substance.

**SARA**

Superfund Amendments and Reauthorization Act of 1986. SARA is a US regulation concerning emergency response plans and the Right-to-Know Act. SARA is administered by the Environmental Protection Agency.

**SARA 313**

The SARA 313 Reportables List is a yearly report of emissions to the air, land, and water of materials designated by SARA Title III, Section 313. Statements about these materials must be reported on MSDSs.

**STEL**

Short-term Exposure Limit. The maximum concentration of a material that you can be exposed for 15 minutes.

**TCLo**

Toxic Concentration Low. The lowest concentration of a material in air that humans or animals have been exposed for any given period of time, that has produced any toxic effect in humans, or produced a carcinogenic, neoplastigenic, or teratogenic effect in animals or humans.

**TDG Act**

Transportation of Dangerous Goods Act. Canadian legislation.

**TDLo**

Toxic Dose Low. The lowest dose of a material introduced by any route, other than inhalation, over any given period of time, and reported to produce any toxic effect in humans or to produce carcinogenic, neoplastigenic, or teratogenic effects in animals or humans.

**Teratogen**

A substance that causes birth defects.

**TLV**

Threshold Limit Value. The maximum concentration of a material that a worker can be exposed to during an eight hour day.

**TLV-C**

Ceiling Threshold Limit Value. The maximum concentration of a material that a worker can be exposed to under any conditions.

**Toxic**

A substance that has a particular lethal dose.

**Toxic Dose**

The amount time and concentration of a substance that you can be exposed to under specific conditions.

**Toxic Effects**

Toxic effects are the known hazardous effects of a chemical substance, such as allergic or carcinogenic effects.

**TSCA**

Toxic Substances Control Act. A US law regulated by the Environmental Protection Agency (EPA) to control risks to human health and the environment. The EPA issues a list of substances called the TSCA Inventory.

**UN Number**

United Nations number. Assigned to hazardous materials to identify them during shipping and transportation.

**Vapor Density**

The relative weight of a vapor compared to air.

**Vapor Pressure**

The pressure a vapor exerts above its own liquid in a closed vessel.

**WHMIS**

Workplace Hazardous Materials Information Service. A Canadian system for distributing information about hazardous materials in the workplace.



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