

data sheet

ORACLE PROCESS MANUFACTURING REGULATORY MANAGEMENT 11i

Oracle® Process Manufacturing Regulatory Management, a regulatory information management tool, automates the creation and maintenance of hazardous materials documentation to support compliance with industry and government regulations. Oracle Process Manufacturing Regulatory Management is part of Oracle Process Manufacturing (OPM), an integrated set of applications that are engineered to work together.

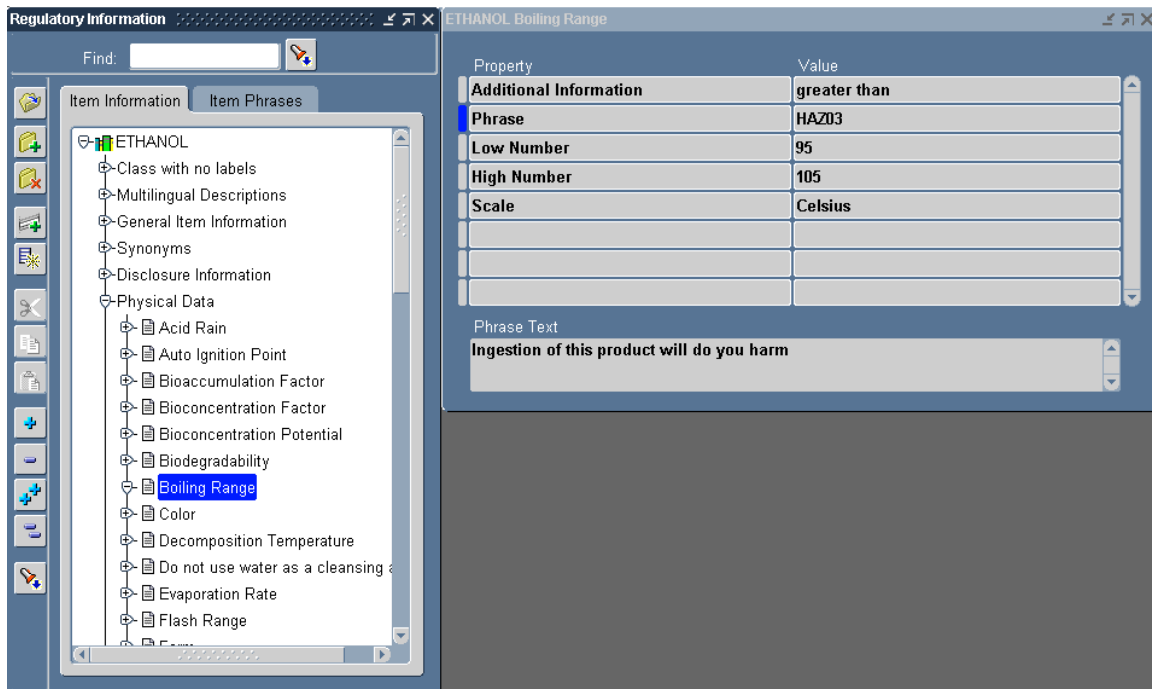
Quickly Respond to Regulatory Requirements with a Centralized, Flexible System

Communicating the regulations governing hazardous chemicals is an important and labor-intensive business process. You must know what types of hazardous chemicals your company has, where they are located, and what to do in case of an accident. Managing this information is critical and extremely difficult, as chemicals are moved throughout your organization and combined in the manufacturing process to create new ones. With web-based Oracle Process Manufacturing Regulatory Management, you can now track regulated materials and their attributes and ensure that appropriate documents are created when such products are developed or manufactured.

Hazardous Material Reporting

Oracle Process Manufacturing Regulatory Management allows you to record the hazardous material content of your products and raw ingredients using European calculation rules. You can use these values in the ingredient, intermediate, and product levels to report the vapor pressure, boiling and flash ranges, Department of Transportation Flammability Class, Hazardous Material Information System and National Fire Protection Association classifications.

You can also record the results of your own calculations to account for the appearance or disappearance of hazardous ingredients as the result of reactions in the production process.



Store and easily find regulatory attributes of an item using the Regulatory Information navigator window.

Regulatory Documentation Authoring and Management

Oracle Process Manufacturing Regulatory Management automates your document creation and management processes, helping ensure your employee's well-being and your business' compliance with government regulations. You can build standard and customizable Material Safety Data Sheets (MSDS) from a single data repository, print them in the language preferred by the customer, and send them to multiple addresses. Documents can be generated either as a result of ad hoc requests or from orders or shipments entered into the Oracle Process Manufacturing Sales Management application. All of these documents can be printed standalone or together, and complete document dispatch history is maintained.

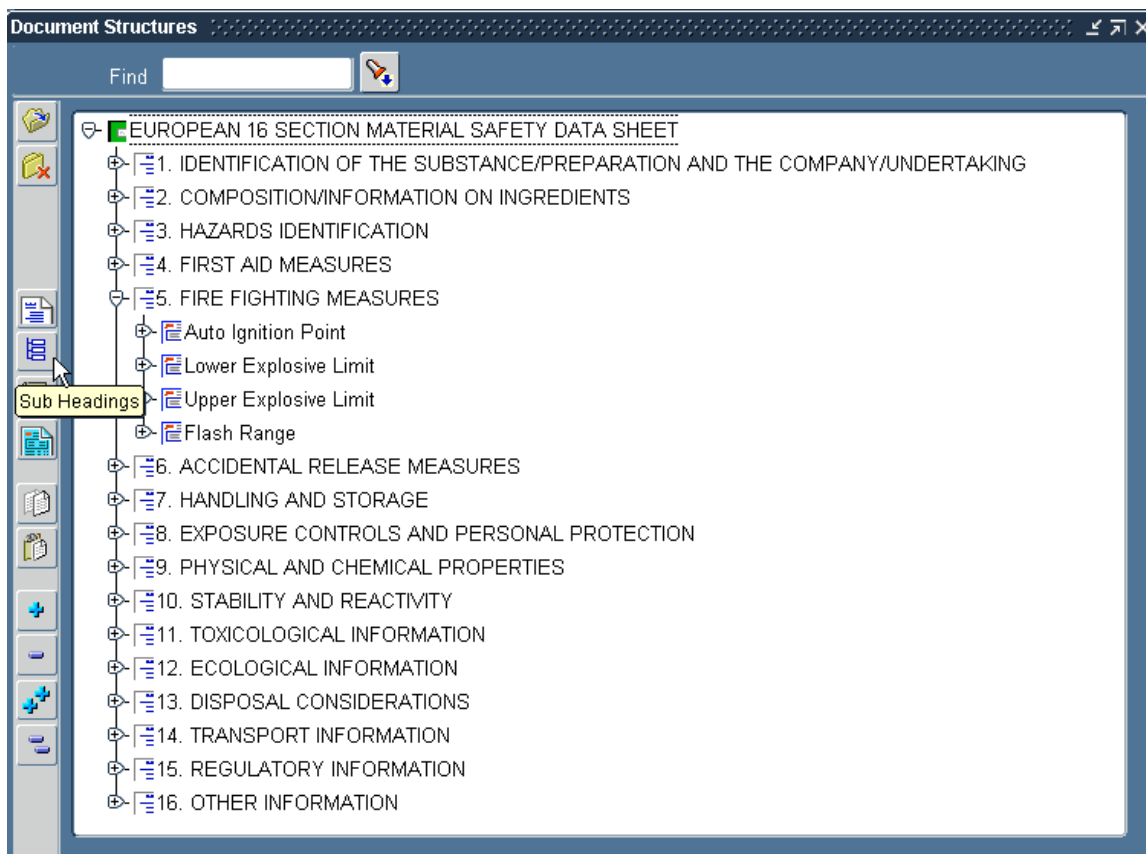
You can also use Oracle Process Manufacturing Regulatory Management to inquire and report on current documents as well as historical information. Inquiries, such as what products use a specific ingredient, can be executed quickly and easily.

Document Definition and Audit Trail

Oracle Process Manufacturing Regulatory Management enables you to easily define and build multiple document types and control the level of ingredient disclosure—to meet customer, business, or country specific requirements. You can create standard Material Safety Data Sheet documents and modify them to fit your business' requirements, as required by different countries, including:

- United States, (ANSI Z.400 16 Section)
- Canada (Workplace Hazardous Material Information System 16 Section)
- European Union (16 Section)

You can also build your own technical documents such as Technical Data Sheets, and Volatile Organic Compound (VOC) data sheets to provide additional technical information. Once you create a document, you can link it to a customer and include multiple addresses. For example, at your customer's request, you could link your documents, so that your customer's headquarters, plant site, and local emergency response center all receive copies of the MSDS when you ship your product to their plant. If you create or change a document, Oracle Process Manufacturing Regulatory Management retains a full history of old document versions.



Customize a template for printing your MSDS by using the Document Structures navigator window.

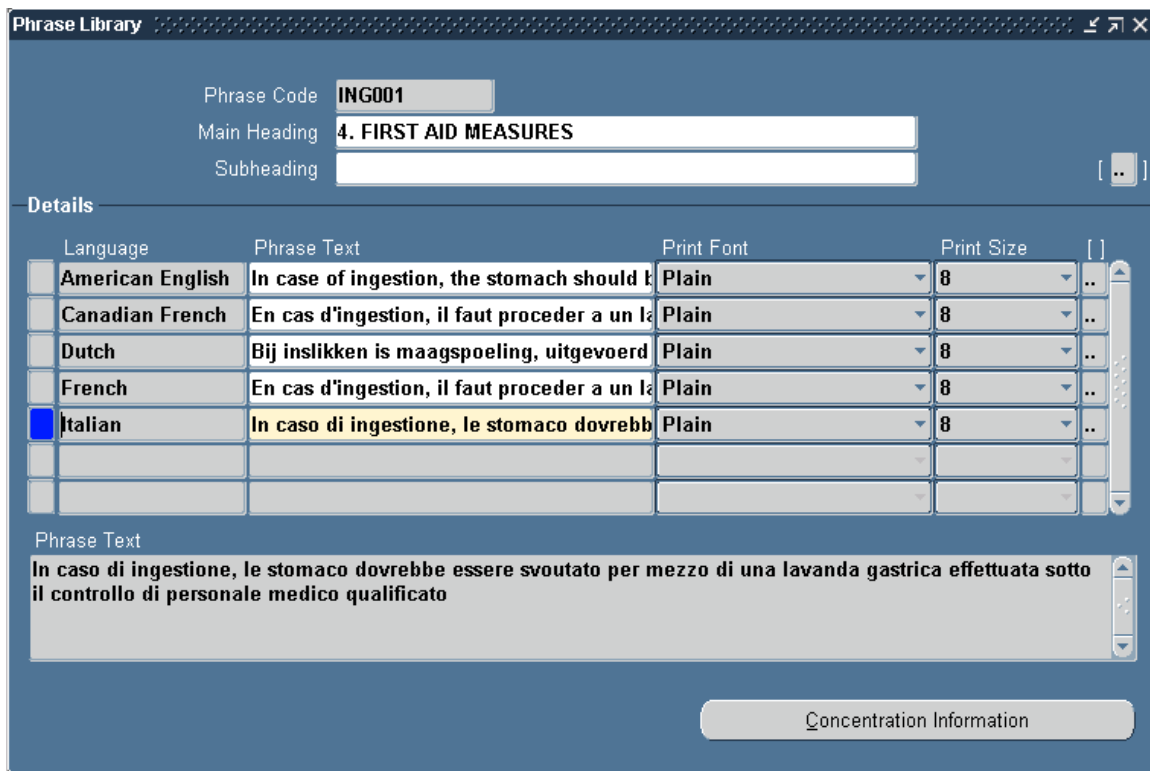
Enabling Multiple Languages

In addition to defining the document structure, you may also change all the documents' labels, headings, and specific section contents on a Material Safety Data Sheet, such as ingredient concentration, toxicity and exposure level reporting, so that they are maintained in multiple languages. The ability to control the language appearing on the document is maintained at the customer shipping level.

Standard Phrasing

Oracle Process Manufacturing Regulatory Management can maintain a standard phrase library, in which you may store text, such as emergency response procedures. You can assign these phrases

to multiple ingredients, products, and/or documents. Using business rules, you can also designate different text phrases for different concentrations of the same ingredient.



Standardize common regulatory text phrases using the Phrase Library.

Rule-Based Dispatch Management

Rule-based dispatch frequency assures that you are sending out the right documents at the right time, based on government regulations and customer specifications. Once a document is produced, a full dispatch history is maintained by the system for inquiry and reporting purposes. Regulatory Management provides a seamless and easy method of sending regulatory documentation to your customers through your standard shipping process.

Oracle E-Business Suite—The Complete Solution

Oracle E-Business Suite enables companies to efficiently manage customer processes, manufacture products, ship orders, collect payments, and more—all from applications that are built on a unified information architecture. This information architecture provides a single definition of your customers, suppliers, employees, products—all aspects of your business. Whether you implement one module or the entire Suite, Oracle E-Business Suite enables you to share unified information across the enterprise so you can make smarter decisions with better information.

KEY FEATURES

Integrated Regulatory Management

- Implement as a stand alone application or fully integrated with other Oracle Process Manufacturing modules, including Inventory Management, Formula Management, and Order Fulfillment
- Reuse information, such as customer addresses
- Create appropriate documents when new products are developed or manufactured
- Ensure that all required documents are sent to your customers

Hazardous Material Reporting

- Define and measure hazardous materials content in products
- Provide emergency procedures for hazardous materials disposal or spillage

Document Authoring and Management

- Create and customize documents to support regulatory compliance
- Support multiple document types, including country-specific standard documents
- Build custom data sheets to provide additional technical details
- Control level of disclosure of ingredient concentrations, toxicity, and exposure levels
- Simplify reuse of text with standard phrasing
- Support multiple languages per customer
- Print documents on request or as a result of entering orders or shipments
- Maintain an audit trail of document versions
- Send appropriate regulatory documentation to customers in a timely manner
- Maintain document dispatches

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