Basic Hazard Communication

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Why Chemical Hazard Communication

- **Before** handling chemicals it is **essential** to obtain data on properties related to health, safety and environment of all chemicals, including IPI & API

- Communication at different levels using different tools

- Minimum requirements included in IH Maturity Ladder: process, availability, guard quality, training
... Essential part of a Chemical Substance Management Program

Chemical Substance Management

- Training
- Risk- and Hazard Assessment
- Exposure Monitoring
- Medical Surveillance
- Handling and Transport
- Spill Control
- Storage of Chemicals
- Hazard Communication

May 14th 2013
‘All substances are poisons, there is none which is not a poison. The right dose differentiates a poison and a remedy.’

Paracelsus (1493-1541)

- **ALL** chemicals have the ability to be toxic in high enough amounts.
- **Hazard** *(toxicity)* - the *inherent ability* for a chemical to produce adverse effects in a biological system.
- **Risk** - the *probability* that a substance will produce harm under certain conditions of use/exposure.
- **Exposure** - Contact with a chemical or mixture such that a dose may be delivered. Exposure occurs when a chemical comes in contact with the skin, is inhaled, swallowed or injected into the skin by a sharp object.
Tools Chemical Hazard Communication

- Safety Data Sheets
- Summary sheets employees
- Labels on each chemical
- Warning signs
- Site Inventory
Safety Data Sheet (SDS)

• Also called Material Safety Data Sheet (MSDS)

• Document: 16 chapters
  1. identification of substances/mixture
  2. hazard identification: Hazard & Precautionary statements
  4. first aid
  6. accidental release
  7. handling & storage
  8. exposure control/personal protection
  9. physical & chemical properties
  11. toxicological information
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

FENTANYL (N*)

Version 1.15  Revision Date 2013-04-03  Print Date 2013-04-17

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : FENTANYL (N*)
Substance name : FENTANYL
Substance No. : 207-113-8
Product code : 8910
Reference number : JNJ-59585-AAA
R304253

1.2 Relevant identified uses of the substance or mixture and use advised against

Use of the Substance/Mixture : Active substance, Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company : Janssen Pharmaceutica NV
Tumhoutseweg 30
2340 Beerse
Belgium
Telephone : +3214502111
Telefax : +3214502841
E-mail address : RA-JANSE-SAFETYDA@JANSE.JNJ.COM

1.4 Emergency telephone number : +32 14 602444

2. Hazard identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Acute toxicity, Category 2 H300: Fatal if swallowed.
Acute toxicity, Category 2 H310: Fatal in contact with skin.
Acute toxicity, Category 2 H330: Fatal if inhaled.
Chronic aquatic toxicity, Category 3 H412: Harmful to aquatic life with long lasting effects.

Classification (67/548/EEC, 1989/45/EC) 1 / 11

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms :

Signal word : Danger

Hazard statements : H300 Fatal if swallowed.
H310 Fatal in contact with skin.
H330 Fatal if inhaled.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : Prevention:
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P310 Immediately call a POISON CENTER or doctor/ physician.
P330 Rinse mouth.
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician.
P302 + P350 IF ON SKIN: Gently wash with plenty of soap and water.
P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

2.3 Other hazards

3. Composition/information on ingredients

3.1 Substances

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS-No.</th>
<th>Concentration [%]</th>
</tr>
</thead>
</table>

2 / 11
Summary sheet

• Summary of information relevant for the employee
• Properties, characteristics: safety, health, environment
• Hazardous properties
• Safety precautions (PPE)
• Emergency response, spill
# Safety Card

**fentanyl [N]**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>R-No.</td>
<td>6004263</td>
</tr>
<tr>
<td>CAS-No.</td>
<td>437-38-7</td>
</tr>
<tr>
<td>Date of Issue</td>
<td>2013-04-03</td>
</tr>
<tr>
<td>UN-No.</td>
<td>35685-AAA</td>
</tr>
<tr>
<td>UN 2811, 6.1,1</td>
<td></td>
</tr>
<tr>
<td>Print Date</td>
<td>2013-04-17</td>
</tr>
<tr>
<td>Version</td>
<td>1.14</td>
</tr>
<tr>
<td>Components</td>
<td>fentanyl [N] (437-38-7)</td>
</tr>
</tbody>
</table>

## Danger

**PBOEL-HHC: 4**

Narcotic (lab register)

## Characteristics

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total formula</td>
<td>C22H28N2O</td>
</tr>
<tr>
<td>Molecular Mass</td>
<td>336.48 g/mol</td>
</tr>
<tr>
<td>Form</td>
<td>solid</td>
</tr>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Flash point</td>
<td>no data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>not applicable</td>
</tr>
<tr>
<td>Melting Point</td>
<td>86.7 °C</td>
</tr>
<tr>
<td>Ignition temperature</td>
<td>no data available</td>
</tr>
<tr>
<td>LEL</td>
<td>no data available</td>
</tr>
<tr>
<td>UEL</td>
<td>no data available</td>
</tr>
<tr>
<td>Decomposition</td>
<td>170 °C</td>
</tr>
<tr>
<td>Density</td>
<td>no data available</td>
</tr>
<tr>
<td>Vapour Pressure</td>
<td>no data available</td>
</tr>
<tr>
<td>Vapour Density</td>
<td>no data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>0.25 g/l</td>
</tr>
<tr>
<td>Resistivity</td>
<td>no data available</td>
</tr>
<tr>
<td>Conductivity</td>
<td>no data available</td>
</tr>
<tr>
<td>pH value</td>
<td>no data available</td>
</tr>
<tr>
<td>Prevention Code</td>
<td>V, CLP/Prot</td>
</tr>
<tr>
<td>OEL</td>
<td>0.0001 mg/m³</td>
</tr>
</tbody>
</table>

## Hazards

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>may cause the following symptoms:</td>
</tr>
<tr>
<td></td>
<td>- Lowered blood pressure</td>
</tr>
<tr>
<td></td>
<td>- Cardiac arrest</td>
</tr>
<tr>
<td></td>
<td>- Coma or death</td>
</tr>
<tr>
<td></td>
<td>- Skin contact may cause the following symptoms:</td>
</tr>
<tr>
<td></td>
<td>- Dermal absorption</td>
</tr>
</tbody>
</table>

## Personal Protective Equipment

- **Eye protection**: Respirator with a full face mask
- **Hand protection**: Nitrile rubber: Protective gloves
- **Body protection**: Closed work clothing, disposable one-piece overall with integral hood
- **Respiratory protection**: Respirator with a full face mask ABEK P3
- **Laboratory**: Follow procedure: “Working with active pharmaceutical ingredients in labs.”

## Safety Measures

Ensure all equipment is electrically grounded before beginning transfer operations. Avoid dust formation.

## Emergency Telephone Number

- **Beeze**: +32 (0) 14 60 2444
- **Geel/Olen**: +32 (0) 14 60 4444

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Data responsible: RA-JANBE-SAFETY@JANSSEN.COM
Labels

• Primary, initial source of warning for employees when handling hazardous chemical substances

• Mandatory on each chemical package (container, bag, bottle,...)

• Includes appropriate hazard warnings

• Identification of the chemical and identification of hazardous component(s)

• Name, address, and telephone number of the chemical manufacturer, importer, or responsible party (e.g. principle investigator)
For research use only.

CAS #: 437-38-7  JNJ #: 35685-AAA
fentanyl (N+*)

Danger
H300 Fatal if swallowed. H310 Fatal in contact with skin. H330 Fatal if inhaled. H412 Harmful to aquatic life with long lasting effects.
Wear protective gloves/ protective clothing/ eye protection/ face protection. Immediately call a POISON CENTER or doctor/ physician. Rinse mouth. IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician. IF ON SKIN: Gently wash with plenty of soap and water. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

Janssen Pharmaceutica NV
Turnhoutseweg 30
B-2340 Beerse
+3214602111

RA-JANBE-SAFETYDA@JANBE.JNJ.COM

SAP ID: 100000001596  Contents: .........................
Warning signs

• Very brief information of hazards permanently in place
• Hazard labels chemicals tank farm
• Identification and flow direction pipe lines
• Chemical storage
Good examples labels piping

= content + flow direction + uniform colour code
Pictograms
Inventory

• List with complete overview of all chemicals stored on site

• SHOULD BE
  – Adequately detailed
  – Up to date
  – Available and easily accessible
  – At the work place

• TO ENSURE
  – Immediate information about the storage (emergency)
  – Immediate knowledge about the chemical risk
  – Compatibility storage
  – Chemical storage management
PROCESS EXAMPLE

Product added in the local department inventory list:
Designation, code, storage, risk

<table>
<thead>
<tr>
<th>DESIGNATION</th>
<th>CODE</th>
<th>STOCK MOYEN</th>
<th>E</th>
<th>F</th>
<th>O</th>
<th>T</th>
<th>Xn</th>
<th>C</th>
<th>Xl</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acétone HPLC</td>
<td>5</td>
<td>0</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acétone PA</td>
<td>5</td>
<td>0</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acétonitrile HPLC</td>
<td>13</td>
<td>30L</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Product added or quantities updated at the storage area:
Designation, code, storage, risk

<table>
<thead>
<tr>
<th>DESIGNATION</th>
<th>STOCK MOYEN</th>
<th>E</th>
<th>F</th>
<th>O</th>
<th>T</th>
<th>Xn</th>
<th>C</th>
<th>Xl</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acétone HPLC</td>
<td>200 L</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isopropyl alcohol</td>
<td>200 L</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chloroform</td>
<td>600 L</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cyclohexane</td>
<td>200 L</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethyl acetate</td>
<td>200 L</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Méthanol</td>
<td>200 L</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tolérène</td>
<td>200 L</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**PROCESS EXAMPLE**

**MSDS & process risk assessment**

**MSDS summary sheet** *(CAS nb, SAP ref, Pictogram, R&S phrases, ...)*

Available for the whole site on intranet *(research mode by key word, risk, reference, direct link with SAP, link with full MSDS scan, MSDS internet link, supplier, ...)*

New product added in inventory list &/or SAP

New Product introduction
PROCESS EXAMPLE

Chemical informations

At site level through intranet

At local department with the inventory list

At storage area with the storage list

At the chemical place with the risk information (emergency)

On the chemical with the label + the summary sheet

Inventories are updated annually

Chemical Hazard Communication May, 14th 2013 18
### Minimum requirements included in IH ML

<table>
<thead>
<tr>
<th>1.1 Employees  received general safety <strong>training</strong> related to chemicals (hazard symbols, basic physico chemical properties, link to health effects).</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 <strong>Site Management and staff functions</strong> (project &amp; process engineers) received an overview <strong>training</strong> on Industrial Hygiene and the impact they can have.</td>
</tr>
<tr>
<td>1.2 A <strong>trained person</strong> responsible for the Chemical Hazard Assessment &amp; Communication Program of basic elements (SDS, inventory, labeling, training) is <strong>appointed</strong>.</td>
</tr>
<tr>
<td>2.1 Employees  <strong>received training</strong> in the hazards, handling, PPE, storage and disposal of chemicals and mixtures in their workplace or area. Specific focus is put on human carcinogens (if applicable) and API/IPL.</td>
</tr>
<tr>
<td>2.1 Employees are <strong>trained</strong> and know how to <strong>react in case of a chemical exposure with specific signs &amp; symptoms</strong> (fe irritation eye or skin, burns, inhalation - difficult breathing)</td>
</tr>
<tr>
<td>2.3 <strong>Safety Data Sheets</strong> are available for chemicals and mixtures in use and stored</td>
</tr>
<tr>
<td>2.3 A <strong>summary sheet</strong> with the most relevant physico chemical &amp; safety properties (such as OEL, required PPE, ...) are available at the workplace (preferred visually displayed).</td>
</tr>
<tr>
<td>2.3 Each chemical and mixture container (tank, drums, pail, bag, bottle, ...) has a <strong>label</strong> that identifies the contents and lists specific safety information (at least hazard symbols).</td>
</tr>
<tr>
<td>2.3 Each pipe is labeled with the chemical name of their content or identified by a site specific color code and the flow direction is indicated. Each dispensing valve dedicated to a chemical agent is labeled with the chemical name.</td>
</tr>
<tr>
<td>2.4 A formal procedure (process) must be in place to ensure that all <strong>new chemicals</strong> or mixtures are <strong>evaluated</strong> to their physical and health hazards <strong>before introduction</strong> on site (Known human carcinogen, permit required, banned, explosive, impact on environment).</td>
</tr>
<tr>
<td>2.4 The organization has developed a process to assure <strong>proper storage</strong> of chemicals (incompatible chemicals, avoid contact water, temperature conditions, ventilation).</td>
</tr>
<tr>
<td>3.1 An <strong>inventory</strong> of chemicals and mixtures is available and up to date</td>
</tr>
<tr>
<td>4.4 SDS are available on request <strong>24 hrs a day</strong>.</td>
</tr>
<tr>
<td>6.1 A system is in place to <strong>periodically check</strong> if the SDS is still up to date</td>
</tr>
<tr>
<td>6.1 <strong>Periodic inspections</strong> are conducted to ensure that labels are in place, in good condition, legible and include the required information</td>
</tr>
<tr>
<td>6.1 <strong>Periodic Chemical Hazard Communication training</strong> is provided to the employees</td>
</tr>
</tbody>
</table>
Hazard communication
Active, pharmaceutical ingredients & intermediates

- Occupational Exposure Limit
- Hazard banding
- Notations
Definitions

- **OEL-TWA:**
  *Occupational Exposure Limit – Time Weighted Average*
  Airborne concentrations of substances that will not result in adverse effects to most healthy workers, exposed for 8 hours per day, 40 hours per week. Most OELs are established as an 8-hour, time-weighted average.

- **OEL-STEL:**
  *Occupational Exposure Limit – Short Term Exposure Limit*
  Occupational Exposure Limit Short-Term Exposure Limit. A 15-minute, time-weighted average exposure, which should not be exceeded at any time, nor repeated more than four times daily with a 60-minute rest period, required between each STEL exposure.
Definitions

• HHC
\textit{Health Hazard Category}
A classification system used to assign materials into one of health hazard categories of increasing severity based upon their inherent pharmacological and toxicological properties

• J&J = PBOELHHC
1A: 3000 – 1000 \mu g/m^3
1B: 1000 – 100 \mu g/m^3
2: 100 – 20 \mu g/m^3
3A: 20 – 5 \mu g/m^3
3B: 5– 0.5 \mu g/m^3
4: < 0.5 \mu g/m^3
Notations

- **Skin Notation**: highlights the potential for significant absorption through the skin.

- **DSEN**-Dermal Sensitizer: highlights the potential for a compound to cause delayed allergic skin reactions (sensitization), such as wheals and rashes.

- **RSEN**-Respiratory Sensitizer: highlights the potential for a compound to cause delayed allergic reactions (sensitization), such as shortness of breath, asthma and anaphylaxis.

- **REPRO**-Reproductive Effector: highlights the potential for a compound to have adverse effects on reproduction and fetal development.

- **CAR**-Carcinogen highlights the carcinogenic properties of a compound.
Thank You

Janssen Campus Belgium

Michel Vangeel