Global GHS Training Course

No.3 - Korea GHS Feature and Local Regulations

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- Has 350+ employees and annual revenue approximately 50 M USD;
- Has branch offices in Dublin(Ireland), Arlington(US), Seoul (Korea), Nanjing(China), Beijing(China), Hangzhou(China);
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Contents

1. Korean GHS
2. Background of Korea REACH
3. Korea REACH Registration
4. Registration of New Chemicals
5. Summary
Korean GHS
## Korea GHS at a Glance

<table>
<thead>
<tr>
<th>Areas</th>
<th>Related regulation</th>
<th>Authority</th>
<th>Standards</th>
<th>UN GHS revision version</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>South Korea</td>
<td>K-REACH</td>
<td>Chemical registration</td>
<td>Ministry of Environment</td>
<td>Notice No. 2020-8</td>
<td>4th</td>
</tr>
<tr>
<td></td>
<td>K-BPR</td>
<td>Authorization of active substance and biocidal product</td>
<td>Ministry of Environment</td>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>This will be revised fully according to latest UN GHS revision version and especially CBI part</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>For Health hazards, need to comply with MoE Notice No. 2020-8</td>
</tr>
</tbody>
</table>
SDS Requirements

• Korea has also adopted standard 16-section SDSs

• Confidential business information (CBI): Substance name, CAS or Content (%)

• Hazardous substances must be fully disclosed in Section 3

• If there is any changes in SDS, the supplier must provide the latest version of the SDS to the buyer

• Must indicate the concentration range within 5%

• If the contents are less than 5%, the lower limit shall be indicated as follows: >=1% "(0.1% for carcinogens and germ cell mutagens, 0.2% for respiratory sensitizers, and 0.3% for reproductive toxins"
SDS Requirements

OSHA 2019 Amendment

• Submit safety data sheets to MoEL before production or import (enforcement 15\textsuperscript{th} January 2021)

• Composition info

- **Option 1**: 100\% composition information (including non-hazardous substances)

- **Option 2**: Hazardous substances only + separate document with non-hazardous substances

- **Option 3 (imported products)**: Hazardous substances + statement signed by foreign companies stating all non-disclosed substances are non-hazardous
Label Requirements

• Labelling requirements issued by the MoEL’s (For Dangerous Goods, can refer to RTDG)

• **Product identifier must be consistent with SDSs**

• Signal word: Warning or Danger

• Up to 4 pictograms can be attached (if more than 5)

• Hazard statements are required, similar statements are combined and repeated statements are removed
Label Requirements

• Precautionary statements: Up to 6 p-statements required. Refer to the SDS

• Must contain the contact info of Korean legal entity

• In general the Korean language must be required. But this is not required for lab and research chemicals

• Substance name and foreign supplier's contact info can be written in English.

• For a package less than 100ml or 100g the hazard and precautionary statements can be omitted by letting reader refer to the SDS.
## Label Size Requirements

<table>
<thead>
<tr>
<th>Capacity</th>
<th>Size of label</th>
<th>Size of pictogram</th>
</tr>
</thead>
<tbody>
<tr>
<td>$500 \text{ L} \leq \text{Capa.}$</td>
<td>$450 \text{ cm}^2$</td>
<td>✓ 1/40 of surface area; ✓ Min. 0.5cm$^2$</td>
</tr>
<tr>
<td>$200 \text{ L} \leq \text{Capa.} \leq 500\text{L}$</td>
<td>$300 \text{ cm}^2$</td>
<td></td>
</tr>
<tr>
<td>$50 \text{ L} \leq \text{Capa.} \leq 200\text{L}$</td>
<td>$180 \text{ cm}^2$</td>
<td></td>
</tr>
<tr>
<td>$5 \text{ L} \leq \text{Capa.} \leq 50\text{L}$</td>
<td>$90 \text{ cm}^2$</td>
<td></td>
</tr>
<tr>
<td>Capa. $\leq 5\text{L}$</td>
<td>$&gt;5%$ of area</td>
<td></td>
</tr>
</tbody>
</table>
### Label Example

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Signal Word</th>
<th>Hazard Statements</th>
<th>Precautionary Statements</th>
<th>Prevention Information</th>
<th>Response Information</th>
<th>Storage Information</th>
<th>Disposal Information</th>
<th>Supplemental Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pictogram</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
02
PART

K-REACH Background
Legislation History of K-REACH

- **Enforcement of K-REACH**: Jan 1st 2015
- **Pre-Announcement of K-REACH Amendment**: Dec. 28th 2016
- **Public Commenting Period**: Feb. 6th 2017
- **Intro. of Amendment V2**: Feb. 15th 2017
- **NA hearing Environmental and Labor Committee “Passed” in Jan 2018**: Sept. 2017
- **Jan 1st 2019**
K-REACH Key Authorities

MOE
Ministry of Environment
Responsible for the registration and evaluation of chemical substance under this Act.

KECO
Korea Environment Corporation
Responsible for pre-registration submission and exemption confirmation

KCMA
Korea Chemicals Management Association
Provide a channel for communication between the authority and the industry.

NIER
The National Institute of Environment
Responsible for dossier evaluation
K-REACH System

- Existing chemical (> 1t/y) → PEC registration
- Pre-registration
- Registration
- Hazard evaluation
- Risk assessment

- New chemical
  - < 100 kg/y → Notification
  - >= 100 kg/y
- Toxic substance (969)

- Authorization substance
  - Restricted (12)/prohibited (60) substance
Substances Exempt Under K-REACH
Substances controlled by other laws and regulations (confirmation not required)

1. Radioactive substances under the 「Nuclear Safety Act」
2. Medicines and non-pharmaceutical items under 「the Pharmaceutical Affairs Act」
3. Narcotics under 「the Narcotics Control Act」
4. Cosmetics and raw materials used for cosmetics under 「the Cosmetics Act」
5. Pesticides and technical ingredients under 「the Pesticide Control Act」
6. Fertilizers under 「the Fertilizer Control Act」
7. Foods, food additives, appliances, containers, and packages under 「the Food Sanitation Act」
8. Livestock feed under 「the Control of Livestock and Fish Feed Act」
9. Explosives under 「the Control of Firearms, Knives, Swords, and Explosives, etc. Act」
10. Military supplies (excluding conventional items) under 「the Act on the Management of Military Supplies」
11. Functional health foods under 「the Functional Health Foods Act」
12. Medical devices under 「the Medical Devices Act」
13. Hygiene products under 「the Hygiene Products Control Act」
14. Biocidal substances and biocidal products defined in subparagraphs 7 and 8 of Article 3 of 「the Act on Safety Management of Chemical Products for Daily Use and Biocides」
# Chemicals Exempt from K-REACH Registration

<table>
<thead>
<tr>
<th>Substances exempt from registration (no confirmation required)</th>
<th>Substances exempt from registration (confirmation required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical substance imported together with relevant machineries or equipment for the purpose of trial operation</td>
<td>Chemical substance imported/manufactured for export-only use, including substance imported/manufactured to make export-only products (Note: needs to be done on annual basis)</td>
</tr>
<tr>
<td>Chemical substance imported as already equipped machinery</td>
<td>Chemical reagents (PEC or New Substances tested in Korea)</td>
</tr>
<tr>
<td>Chemical substances in articles with no intended release</td>
<td>Substances for R&amp;D use</td>
</tr>
<tr>
<td>Chemicals excluded from registration or notification (MoE Notice No. 2018-234) Impurities and By-product</td>
<td>Surface treated substances</td>
</tr>
<tr>
<td></td>
<td>Non-isolated intermediates</td>
</tr>
<tr>
<td></td>
<td>On-site isolated intermediates (which can be technically blocked from leakage or exposure)</td>
</tr>
<tr>
<td></td>
<td>Polymer of low concern (PLC).</td>
</tr>
</tbody>
</table>
## Exemption of Very Low Risk Substances

<table>
<thead>
<tr>
<th>Current</th>
<th>New Added</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impurities, by-products</td>
<td>Substance which is gained from other substance in the nature by using manpower, machine, water solubility/ floating (in case of physical application or simple mixing)</td>
</tr>
<tr>
<td>Compost, biofuel, hydrogen, oxygen</td>
<td></td>
</tr>
<tr>
<td>Substances which exists in the nature and its chemical structure is not changed (e.g. Minerals)</td>
<td>Constituent chemicals of human body (e.g. amino acid, bases of which DNA or RNA is composed)</td>
</tr>
<tr>
<td>Substance which is gained from nature resources and its chemical structure is not changed (e.g. vegetable, animal fat)</td>
<td></td>
</tr>
</tbody>
</table>

Substances excluded from registration, notification: 44 substances
K-REACH Registrant/Notifier

<table>
<thead>
<tr>
<th>K-REACH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Korea Manufacturer</td>
</tr>
<tr>
<td>Korea Importer</td>
</tr>
<tr>
<td>Non Korea Manufacturer or Formulator (appoint an OR in Korea)</td>
</tr>
</tbody>
</table>
OR Responsibility

- Overseas Manufacturer
- Only Representative
- Authority
- Domestic Importer

OR Importer:
- Registration/ Notification confirmation letter
- Pre-notification
- MSDS
- Notification result of Priority Management chemicals
- OR confirmation letter

- Change is not available under K-REACH currently
- OR Appointment takes 7 working days
Post registration

• Update importer list and relevant use information
• Communication with Korean importers and non-Korean exporter
• Data recording and Keeping for registration
• Supplement of materials
• Update the submitted information
• SDS update
• Change of registrant-the change in company name, address, representative, etc.
Penalty

5% of Total Sales or less will be fined if manufacturer/ importer doesn’t comply with K-REACH!

* Total sales = Average three-year annual sales before violation.
* If it’s hard to estimate total sales, it may be charged up to one billion won.
Korea REACH Registration
### K-REACH Registration


#### Chemical Search

<table>
<thead>
<tr>
<th>CAS No.</th>
<th>Chemical Name</th>
<th>KE No.</th>
<th>Phase-in substance subject to registration</th>
<th>Toxic substance</th>
<th>Restricted substance</th>
<th>Prohibited substance</th>
<th>Substance requiring preparation for accidents</th>
<th>Percentage &amp; Regulatory Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>68650-00-0</td>
<td>Fatty acids, tall oil polymers with pentaerythritol, phthalic anhydride and tung oil, oxidized</td>
<td>KE-16170</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50-00-0</td>
<td>Formalin [Other names: Formaldehyde]</td>
<td>KE-17074</td>
<td>1</td>
<td>97-1-345</td>
<td>06-5-5</td>
<td>1</td>
<td>View info</td>
<td></td>
</tr>
<tr>
<td>131500-00-0</td>
<td>Sodium 2-[[2-(dodecyl(oxy)ethoxy)]ethoxy]ethyl sulfate</td>
<td>KE-31442</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
K-REACH Registration Procedure

**Substance**

- **Existing Substance/Non PEC substance**
  - Full Registration
  - Pre-registration and grace period
  - Exemption confirmation

- **PEC substance**
  - Joint submission
  - Individual submission
  - PLC/R&D exemption confirmation

- **New Substance**
  - <0.1t/a: notification
  - ≥0.1t/a: registration
K-REACH Registration Timeline

- **Pre-registration**
  - 1-10t/y
  - 10-100t/y
  - 100-1000t/y
  - ≥1000t/y CMRs (≥1t/y)

- **New Substance (without KE NO.)**
  - 510 PEC Substances
  - Jul. 1st 2018
  - Jan 2019
  - June 2019
  - Dec.31st 2021
  - Dec.31st 2024
  - Dec.31st 2027
  - Dec.31st 2030
Process of K-REACH Late Pre-registration

- Self-declaration on the export volume during last three years;
- Filling in Substance Information Survey;
- Confirming Contract and POA (non-Korean enterprise);
- Preparing Late Pre-registration dossier;
- Sending Late Pre-registration number and completion notice;
- Maintaining Late Pre-registration and updating information (if necessary).
K-REACH-Joint Submission

Form a consortium → Elect a Lead Registrant (LR) → Preparation of registration

Sales of LoA ← Individual application for registration ← Application for registration by the representative
Data Requirement

<table>
<thead>
<tr>
<th></th>
<th>0.1-1 ton/year</th>
<th>1-10 ton/year</th>
<th>10-100 ton/year</th>
<th>10-100 ton/year</th>
<th>&gt; 1000 ton/year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicochemical data</td>
<td>5</td>
<td>8</td>
<td>11</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Health hazard data</td>
<td>2</td>
<td>4</td>
<td>10</td>
<td>11</td>
<td>15</td>
</tr>
<tr>
<td>Environmental hazard data</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>13</td>
<td>19</td>
</tr>
<tr>
<td>Total</td>
<td>9</td>
<td>15</td>
<td>26</td>
<td>37</td>
<td>47</td>
</tr>
</tbody>
</table>

- GLP (Good Laboratory Practice) institutes are required;
- There are 18 GLP institutes in Korea;
- Test reports from EU GLP lab should be acceptable under K-REACH.
K-REACH Registration- Polymer Registration vs PLC

**Polymer**
- Register as whole product
- Acid/base stability test
- GPC test
- Residual monomer content Analysis
- Less data requirements

**PLC**
- Exemption Confirmation
- GPC test
- Residual monomer Content Analysis
New Chemical Registration
## New Chemical Substances Registration or Notification

### Registration
- New chemical substances manufactured or imported ≥0.1 t/a

### Notification
- New chemical substances manufactured or imported <0.1 t/a
  - Annual manufacture / import volume, classification and labeling, use, etc. (including application for confidentiality, proof of exemption from harmful examination, etc., if applicable)

#### Physicochemical and toxicological test data (new chemical substances)

<table>
<thead>
<tr>
<th>Test</th>
<th>0.1~1 t/a</th>
<th>1+ t/a</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.1~1 t/a</td>
<td>1+ t/a</td>
</tr>
<tr>
<td>Physicochemical</td>
<td>(9)</td>
<td></td>
</tr>
<tr>
<td>Physical State</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water Solubility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Melting/freezing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boiling Point</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health Toxicological</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Tox. Oral or Inhalation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ecotoxicology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Tox. Fish or Daphnia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rapid biodegradability</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Data requirements are the same with existing chemical substances
- New substances do not apply data reduction standards
Summary
Summary

- Build an internal inventory system for your products in Korea
- Ensure you choose a competent Only Representative
- Be aware of Late Pre-Registration
- Monitor regulation updates and consortium progress
- Make sure your Korean SDS/ label compliant
- Contact us for future questions
Useful Links

1. Asia-Pacific Chemical Inventory Search System (APCISS):
   http://apciss.cirs-group.com/?l=en-us

2. Regulatory Related Materials Download:
   http://freedoc.cirs-group.com/en

3. Free Webinar Information:
   http://www.cirs-reach.com/events

4. Regulatory News Updates:
   http://www.cirs-reach.com/
K-BPR

Consumer Chemical Products and Biocides Safety Act

Biocides

Active Substance

Apply for approval of active substance

Biocidal Product

Apply for approval of biocidal product

Treated Article

Comply with standards and labeling criteria

Notice of Grace period

Group 1 2019.12.31
Group 2 2022.12.31
Group 3 2024.12.31
Group 4 2027.12.31
Group 5 2029.12.31

Complete the approval process before the end of each grace period.

Consumer Chemical Products subject to safety Check

Check the product to comply with the safety and labeling standards and notify MoE.

More information about K-BPR can be found by clicking the below link:
Q&A Session

Following our event, please always click


to find further updates

Contact Email: service@cirs-reach.com
For our Consultation

Next Webinar: China GHS features and local regulations
Time & Date: (GMT+1) 15:00, July 22nd
Registration still Available
Thank you for your attention