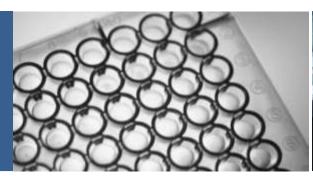


Latest Updates of the South Korean OSHA Amendment





Global Chemical
Regulatory Compliance

www.cirs-group.com



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Who is CIRS?





- CIRS is an individual consulting firm founded in 2007 and headquartered in China;
- Has 200+ employees and annual revenue approximately 30 M USD;
- Has branch offices in Dublin(Ireland), London (UK), Arlington(US), Seoul (Korea), Nanjing(China), Beijing(China), Hangzhou(China);
- CIRS provides regulatory compliance consulting, testing and training services.
- CIRS shares more than 70% Chinese consulting markets;
- Has 4000+ Clients including 300+ oversea companies

CIRS China (HQ)

Add: 11/F., Bldg 1, Dongguan Hi-Tech Park, 288 Qiuyi Rd, Binjiang District, Hangzhou, China

CIRS Europe

Add: CIRS, Regus Harcourt Centre D02 HW77, Dublin, Ireland

CIRS US

Add: #200-092, 3100 Clarendon Blvd., Arlington, VA 22201

CIRS Korea

Add: B-2310, 583, Yangcheon-ro, Gangseo-gu, Seoul, Republic of Korea

CIRS UK

Studio 310, Pill Box, 115 Coventry Road, London, E2 6GG

What is GHS?

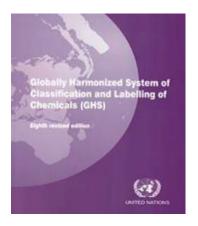


GHS (Globally Harmonised System) of:

Classification

Safety Data Sheet (SDS)

Labelling of chemical substances





Why is GHS Important?

- Documentation for custom clearance
- **❖** Tool of info exchange in supply chain
- Instruction for operation and emergency handling of hazardous chemicals
- Internationally recognised method of product hazard assessment





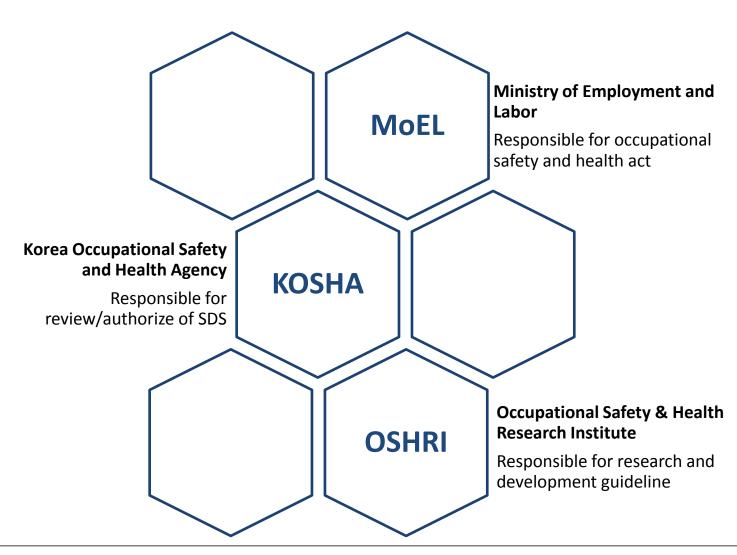


- The Korean GHS Standard: MoEL No. 2020-130
- SDS Submission Process
- K-OSHA: CBI Application & Extension
- Case Studies
- Workflow

1 The Korean GHS Standard: MoEL No. 2020-130



Korean GHS Key Authorities



MoEL Notice No. 2020-130



Ministry of Employment and Labour (MoEL) has amended its standard under the Occupational Safety and Health Act (K-OSHA)

MoEL Notice No. 2016-19 has been updated to MoEL Notice No. 2020-130 as of January 16th, 2021 and is currently in effect

- Korea has adopted the standard 16-section SDS aligning with UN GHS 4th Revision
- The SDS and Label should be authored in the Korean language
- Emergency Contact Info of Korean legal entity (but not the same as 24h number)
- Hazardous ingredients should be listed in section 3
- Apply for CBI before SDS submission, if approved, the CBI authorization number and expiry date should be indicated in section 3 of the SDS
- If there are updates to an SDS, the supplier must provide the latest version to the buyer immediately

MoEL Notice No. 2020-130



NEW!

- 48 categories of use to choose from. See appendix 5 for list of uses and descriptions of use
- Must indicate SDS number issued by MoEL on upper left side
- If CBI is applicable, the 'authorization number' and 'expiry date' provided by MoEL should be stated in section 3
- SDS standards under K-OSHA revised including P/H phrases, added definition of hazardous to ozone layer, clearer definitions of each hazard category etc.
- Not all substances may apply for CBI protection such as prohibited substances, substances requiring permission, hazardous substances subject to management, harmful factors subject to measurement of the work environment, hazardous factors subject to a special health examination and substances having a physical hazard, health hazard or environmental hazard under K-REACH
- The concentration range in section 3 is wider:
 - 1) If concentration is below 25%, the range can be $\pm 10\%$
 - 2) If concentration is equal or above 25%, the range can be $\pm 20\%$

Further Revisions



| Item | Pre-revision | Post-revision | Notes |
|--|--|--|--|
| Scope of chemical substances requiring an SDS? | Hazardous and dangerous chemicals and products containing such chemicals | Hazardous and dangerous chemicals or mixtures | Products containing such chemicals replaced with mixtures – term changed |
| Role in the supply chain requiring an SDS? | Person who transfer or provide relevant chemicals | Persons who manufacture or import relevant substances | Persons who use the chemicals after manufacture/import are included |
| Items which need to be included on the SDS? | Name of the relevant chemical Name or content of all components | Product Name Name or content of hazardous and dangerous chemicals | Product name replaces the term relevant chemical Introduced by UN GHS |

Revised Cut-off Values

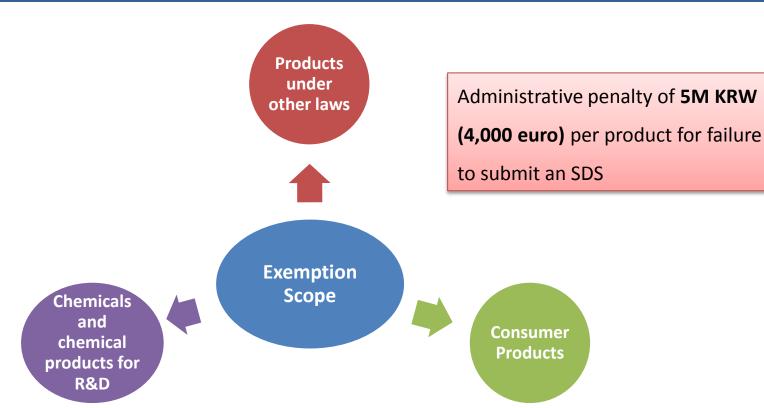


| Classification | Health and environment hazard class and category code(s) | Cut-off limit |
|----------------------|--|---------------|
| Human health hazard | 1. Acute toxicity | 1% |
| | 2. Skin corrosion/skin irritation | 1% |
| | 3. Serious eye damage/eye irritation | 1% |
| | 4. Respiratory sensitisation | 0.1% |
| | 5. Skin sensitisation | 0.1% |
| | 6. Germ cell mutagenicity* 1A & 1B | 0.1% |
| | | |
| | Germ cell mutagenicity 2 | 1% |
| | 7. Carcinogenicity * | 0.1% |
| | 8. Reproductive toxicity* | 0.1% |
| | 9. Specific target organ toxicity – single exposure | 1% |
| | 10. Specific target organ toxicity – repeated toxicity | 1% |
| | 11. Aspiration hazard | |
| Environmental hazard | 12. Hazard to aquatic environment | 1% |
| | 13. Hazard to the ozone layer | 0.1% |

^{*}Substances that are classified and present in the product higher than the cut-off limit must be included in MSDS

New Exemptions to SDS Submission





Products under other laws: dietary supplements (Health Functional Food Act), raw material substance (Act on Safety Control of Radioactive Rays), household chemicals products for general consumers, hygiene products and advanced biomedicines

Labelling



MoEL No.2020-130

- In Korean language
- Options to choose 4 pictograms and 6 precautionary statements if there are more.
- Korean supplier info required
- For low volume(below 100ml), simplified label applied

| Capacity | Size of label | Size of pictogram | | |
|----------------------|---------------------|---------------------------|--|--|
| 500 L ≤ Capa. | 450 cm ² | | | |
| 200 L ≤ Capa. ≤ 500L | 300 cm ² | ✓ 1/40 of surface area; | | |
| 50 L ≤ Capa.≤ 200L | 180 cm ² | | | |
| 5 L ≤ Capa. ≤ 50L | 90 cm ² | ✓ Min. 0.5cm ² | | |
| Capa. ≤ 5L | >5% of area | | | |

2 SDS Submission Process

OR Appointment for non-Korean companies



Non-Korean companies cannot submit an SDS by themselves or apply for CBI

They have two options:

- 1) Korean importer
- 2) Appoint an Only Representative (OR) such as CIRS Korea The OR can only be appointed by the manufacturer or formulator The OR fulfils the role of a domestic importer.

The scope of the OR workload is preparation and submission of MSDS, MSDS CBI application and extension approval, rejected application appeal and delivery of approved MSDS to importers in Korea.

K-OSHA amendment



- K-REACH
- Chemical Control Act (CCA)
- OSHA (2019 amend)
 - New request regarding SDS
 - For Korean manufacturer and importers of hazardous chemical product
 - SDS submit to MoEL
 - Submit the SDS with complete ingredients information in section 3(all hazardous and non-hazardous ingredients listed); or
 - Only hazardous ingredients are listed in section 3. Other nonhazardous ingredients are listed in a separate sheet.; or
 - For IMPORT only, only hazardous ingredients are listed in section 3. A separate sheet signed by overseas manufacturer indicating all other ingredients are non-hazardous. (form No.62)

SDS Submission Method and Grace Period CIRS





- All hazardous chemicals importers and manufacturers in Korea should submit the SDS
 - For newly imported or manufactured chemicals, submit before import/manufacture;
 - For existing chemicals which already authored SDS, following the grace period;
 - Submit through an online IT system;
 - Detailed use is requested.
 - Updated/revised SDS should be re-submitted ASAP.

Grace period

- $\ge 1,000$ ton: by 2022.1.16
- 100-1,000 ton: by 2023.1.16
- 10-100 ton: by 2024.1.16
- 1-10 ton: by 2025.1.16
- <1 ton: by 2026.1.16</p>

Form no. 62 Confirmation of Chemical

※ 색상이 어두운 칸은 신청인이 적지 않으며, []에는 해당되는 곳에 √표를 합니다.

| 접수번호 | 접수일시 치 | 려리일 | 처리기간 | 즉시 | | | | |
|-------------------------------|--|-------------------------|-------------------|-----------|--|--|--|--|
| | ①Only representative | | | | | | | |
| | [] O - OR appointment Company name | CEO | []X ②Industry | | | | | |
| Importers | Business number | Number of staff | | | | | | |
| | Address | | | | | | | |
| | Tel. | (E-mail: Fax, | |) | | | | |
| ③ Category | [] R&D [] Non R&D | | | | | | | |
| <pre> @Product name</pre> | Should match with product name of SDS | | | | | | | |
| Overseas manufactu rers | Company name | Country | | | | | | |
| | Address (T | el . : | |) | | | | |
| ⑤Confirm | I declare that the product doesn't c in Section 3 of SDS. | ontain classified chemi | cal other than | described | | | | |



Letter of Confirmation Example



| Date: |
|---|
| Letter of Confirmation |
| To whom it may concern: |
| Product Name : |
| After careful review of the Certificate of Composition of the above-identified product, I/we here by confirm that all composition of the product, excluding the listed in the MSDS(SDS) do not fall under the harmful factor's classification standards under the Korean Occupational safety and h ealth ACT. |
| Name:(Signature or Seal) Title: Name of Department: |
| Company: Address: |
| Tel: |
| Fax: E-mail |

K-OSHA:CBI Application & Extension

CBI application



- The ingredient name and the exact concentration can be protected.
 - Not all hazardous ingredients can apply CBI.
 - Once approved, authorisation number and expiry date will be replied by MoEL.
 - The original protection period will be 5 years. Applicants can apply for an extension every 5 years (at least 1 month in advance)

Application information

- Applicant info
- CBI reason
- Alternative data (generic name/conc. range)
- 100% ingredient info (substance name+
 concentration) and the hazardous information
- SDS document
- Name and content of chemicals that are not classified
- Other documents required by MoEL

Form no. 63 (via IT system)

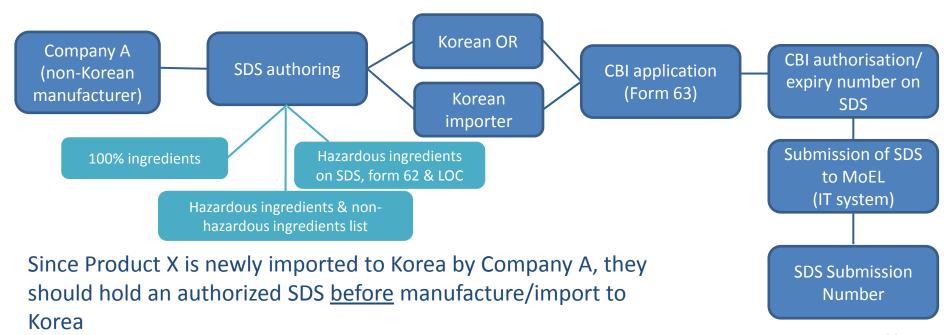
| Form no. 63 CBI [] Approval [] Extension approval | | | | | | | | | |
|---|---|-------------------------------|------------------|-------------|------|-----------|------------|------------------------|--|
| ※ 색상이 어두운 칸은 신청인이 적지 않으며, []에는 해당되는 곳에 √표를 합니다. | | | | | | | (앞쪽) | | |
| 접수번호 | 접 수일시 | 처리 |) <u>S</u> | | | 처리기 | 기간 | 1개월(2주) | |
| Applican | Pusings registration number | | | | | |]; Dinc |]× ndustry | |
| t t | Address Tel. | (E· | (E-mail:) Fax | | | | | | |
| ③ Category | [] Manufacture [|] Import | | [|] R8 | 3D [|] | non-R&D | |
| <pre></pre> | | | | | | | | | |
| | Classified or not | Chemical name (CAS No.) | <u>CB</u> J | Content (%) | | CBJ claim | | Hazards information | |
| | [] O [] X- [] not applicable [] not available | | | X] O[]X | | []O[]X | | | |
| ©Full compositi | [] O [] X-[]not applicable []not available | cable []not available 2. | | X[]0[] | | X[]O[] | | | |
| on | [] O [] X-[] not applicable [] not available | 3. | [] | 0[]X | |] 0[] |]X | | |
| | [] X-[]not applicable []not available | 4. | X[]O[] | | |] 0[] |]X | | |
| | - Number of all composition: - Number of classified chemicals: - Number of CBJ chemicals: | | | | | | | | |
| | Substitute chem | ical name | | | | Substi | tute | content(%) | |
| ® | 1. | | | | | | | | |
| Substitut e data | | | | | | | | | |
| e uata | 3. | | | | | | | | |
| | | would like to | hide | | | | | | |
| ⑦ Hazards informati on | | | | | | | | | |
| ® Approval number | | | | | | | | | |
| - rantoot | | | | | | | | | |



Case Study 1



Company A, an EU manufacturer, produces a chemical product. Their market research shows there is high demand for this product in Korea. They decide to import to Korea for the first time in September 2021. According to K-GHS classification criteria, the product is found to be a mixture of hazardous and non hazardous chemical substances. Company A does not want to share the complete ingredient information so they can maintain a competitive edge. What options are available to Company A?



Case Study 2



Company B is a non-Korean manufacturer of a chemical product. They entrusted CIRS Korea as their OR to author/submit a Korean SDS to MoEL. The SDS was authorized before January 16th 2021. Company B has been selling their product into Korea for the past three years. The aggregate tonnage of the substance imported to Korea in 2020 was 50 tons/year. What should Company B do in order ensure they have a valid SDS for their product?

Since the SDS authorized was before January 16th,2021, they are granted a grace period for updating their SDS according to the updated regulations. Since the annual tonnage of their product in 2020 was in the 10-100 tonnage band, they have until 16/01/2024 to update their SDS. They may choose a Korean OR such as CIRS Korea or their Korean importer to update the SDS for them.

≥1,000 ton: by 2022.1.16

100-1,000 ton: by 2023.1.16

10-100 ton: by 2024.1.16

1-10 ton: by 2025.1.16

<1 ton: by 2026.1.16

Case Study 3



Company C is requested to submit a Korean SDS to MoEL before import to Korea. Company C has done EU REACH registration of the same product in the EU and has a compliant EU CLP SDS available for the product. Can they simply translate the CLP SDS to the Korean language and submit to MoEL?

Translation alone is not enough to comply with K-GHS. The SDS must be authored according to the updated Korean GHS standard MoEL 2020-130. Although there are some similarities between the GHS standards of different countries, they are not the same.

5 Workflow

SDS Submission to MoEL



| *MSDS변호 | AA00241-000000 | 0001 중복검사 | *MSDS 제개정임 | | | | | | |
|---------------|----------------|----------------------|---------------|---------------------|---|--|--|--|--|
| MSDS No. | | Duplication check 추가 | | | | | | | |
| *제품명 | No | 제품명 | | 제품코드 | 삭제 | | | | |
| | 1 | | | | | | | | |
| 용도 | | | | | 현집 | | | | |
| | 회사명 | 추식회사씨아이암에스그(| · 사업자등록번호 | 1828101294 | | | | | |
| | 주소 | 07547 시설 | · 감서구 양천로 583 | 주소검색 | | | | | |
| '제조사/공급자 | TX. | (영창동, 우림블루나인비즈 | 니스센터) 비동2310호 | | | | | | |
| 제조사/창급사 | 전화번호 | 0263478803 | 팩스번호 | 0263478811 | | | | | |
| | 대표자 | 임당식 | 전자우편주소 | kbpr@cirs-group.com | | | | | |
| | 업종 | 그 외 기타 전문. 고 검색 | 근로자수 | 21 | | | | | |
| | | | | | | | | | |
| 구성성분 | | | | | 성분추가 | | | | |
| No (MSDS 미2 | CHERTALES | CAS 번호/MSDS 번호 | *1 | 물질명/제품명 | 함유량(% | | | | |
| (1/10000 11/1 | 3.70 | | | | 범위 | | | | |
| 제품 유해성/위험성 | | | | | 편집 | | | | |
| | | | | | .,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | | | | |
| 파일 첨부 | | | | | | | | | |
| "제품 MSDS | 200,0148 | | | | | | | | |

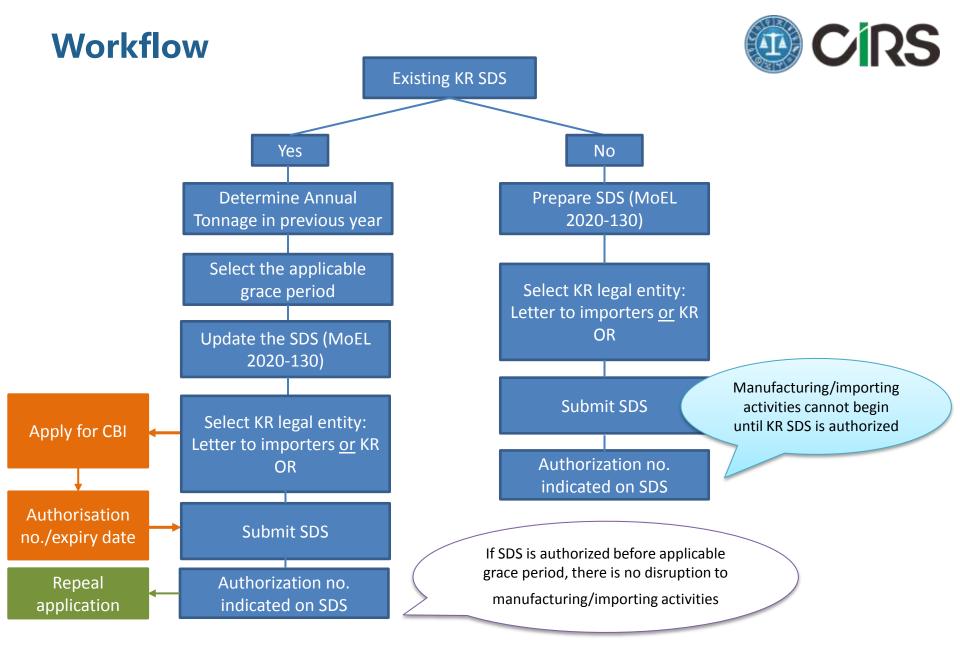


CBI Administration Costs

This fee is only applicable for CBI applications and not SDS submission/OR appointment

(Euro)

| | Large | Large | Medium | Medium | Small | Small |
|----------------------|-------|---------|--------|---------|-------|---------|
| Category | New | Renewal | New | Renewal | New | Renewal |
| Starting fee | 52 | 26 | 26 | 13 | 10 | 5 |
| 1 CBI substance | 82 | 41 | 41 | 21 | 16 | 8 |
| 2 CBI substances | 112 | 56 | 56 | 28 | 22 | 11 |
| 3 CBI substances | 142 | 71 | 71 | 35 | 28 | 14 |
| 4 CBI substances | 172 | 86 | 86 | 43 | 34 | 17 |
| 5 or more substances | 201 | 101 | 101 | 50 | 40 | 20 |



CIRS Services for Korean GHS Compliance CIRS



CIRS Service includes:

- Korean OR service
- Authoring/Review SDS according to the Korean GHS standard (not just) translation)
- CBI application
- CBI extension
- Submit the SDS to MoEL



Thank You

If you have any questions about chemical regulation compliance, please contact your *compliance expert*:

julie@cirs-reach.com

