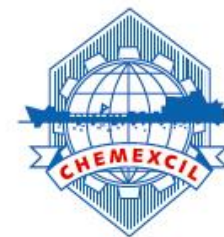


MSDS regulation updates and obligation in South Korea



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Title: Regulatory researcher
Affiliation: GPC Korea
Email:
Ashley@kr.gpcregulatory.com



CHEMEXCIL

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MSDS regulations


MSDS obligations

MSDS preparation & submission

Summary

Material Safety Data Sheet (MSDS)

- A manual of a chemical product (substances or mixtures) for the safe use in workplace
- 16 sections

물질안전보건자료		
고용노동부고시 제 2020-130 호		
인쇄일자: 2022.11.24	MSDS 번호: AA00000-0000000001	개정: 2022.11.24
1. 화학제품과 회사에 관한 정보		
가. 제품명: ABC		
나. 제품의 권고 용도와 사용상의 제한:		
<ul style="list-style-type: none"> - 권고 용도: 윤활유 및 첨가제 - 사용상의 제한: 자로 없음. 		
다. 공급자 정보:		
<ul style="list-style-type: none"> - 회사명: 에스에스에스 코리아 - 주소: 서울특별시 강남구 테헤란로 441 송암 3 빌딩 5층 (네스피스 삼성점) - 전화번호: 070-4641-9856 - 긴급 전화번호: 		
2. 유해성·위험성		
가. 유해성·위험성 분류:		
심한 눈 손상성/눈 자극성 - 구분 2	H319 눈에 심한 자극을 일으킴	
나. 예방조치 문구를 포함한 경고 표지 항목:		
<ul style="list-style-type: none"> - GHS 그림문자: 		
 GHS07		
<ul style="list-style-type: none"> - 신호어: 경고 - 유해·위험문구 - 눈에 심한 자극을 일으킴 - 예방조치문구 - 분진/흙/가스/미스트/증기/스프레이의 흡입을 피하십시오. - 취급 후에는 취급 부위를 철저히 씻으십시오. 		

MSDS regulations

Overview of the MSDS regulations



- Korea Occupational Safety and Health Act (KOSHA)
- Enforcement Decree of KOSHA
- Enforcement Rule of KOSHA
- The Standard of Classification · Labelling of Chemical Substances and Material Safety Data Sheet

Korea Occupational Safety and Health Act (KOSHA)

- Updated: 2021.08.17
- Enforcement: 2022.08.18
- Ministry of Employment and Labor (MOEL)
- To maintain and promote the safety and health of workers
 - By establishing standards for occupational safety and health
 - By clarifying the responsibility to prevent industrial accidents and create a pleasant working environment
- Safety and health management system
- Measures to prevent industrial accidents
- Measures to against harmful or dangerous substances
- Material Safety Data Sheet (MSDS), etc

The Standard of Classification · Labelling of Chemical Substances and Material Safety Data Sheet (MSDS)

- Updated: 2020.11.12
- Enforcement: 2021.01.16
- Ministry of Employment and Labor (MOEL)
- To establish matters necessary for classification of chemicals, MSDS, warning signs and training for workers, etc
- Classification and Labelling
- Placards (warning signs)
- Material Safety Data Sheet (MSDS)
- Approval of alternative data
- Training for workers, etc

Competent authorities



Ministry of Employment and Labor
(MOEL)



Korea Occupational Safety and Health Agency
(KOSHA)

MSDS obligations

Classification and Labelling

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS)
- Fourth revision edition

Physical hazards (16)	Explosive, Flammable gases, Flammable liquids, Flammable solids, Aerosols, Water reactive chemicals, Oxidizing gases, Oxidizing liquids, Oxidizing solids, High pressure gases, Self-reactive substances and mixtures, Pyrophoric liquids, pyrophoric solids, Self-heating substances and mixtures, Organic peroxides, Corrosive to metals
Health hazards (11)	Acute toxicity, Skin corrosion/irritation, Serious eye damage/irritation, Respiratory sensitization, Skin sensitization, Carcinogenicity, Germ cell mutagenicity, Reproductive toxicity, Specific target organ toxicity-single exposure, Specific target organ toxicity-repeated exposure, Aspiration hazard
Environmental hazards (2)	Hazardous to the aquatic environment, Hazardous to the ozone layer

Scope & Exceptions

Scope

- A chemical substance or mixture that might cause health disorders to employees
- Classified based on the Article 104 of KOSHA
 - Physical hazards (16)
 - Health hazards (11)
 - Environmental hazards (2)

Exception

- Specified in other Acts
 - Pesticide Control Act
 - Fertilizer Management Act
 - Medical Devices Act
 - Waste Management Act
 - Cosmetics Act, etc
- Provided mainly to general consumers for daily life
- For R&D

MSDS obligations



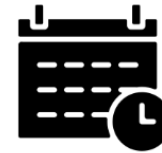
WHO

- Chemical manufacturers and importers of a substance or mixture classified under KOSHA
- Only Representative (OR) appointed by overseas manufacturers



WHAT

- MSDS preparation and submission
- MSDS update and resubmission
- MSDS transfer and provision



WHEN

- Before manufacture or import to South Korea
- Before the deadline

Deadline

Existing MSDS

- Imported and have MSDS before Jan 16th, 2021
- A grace period based on tonnage band

Deadline	Tonnage band
Jan 16th, 2022	Over 1000 tpa
Jan 16th, 2023	100-1000 tpa
Jan 16th, 2024	10-100 tpa
Jan 16th, 2025	1-10 tpa
Jan 16th, 2026	Below 1 tpa

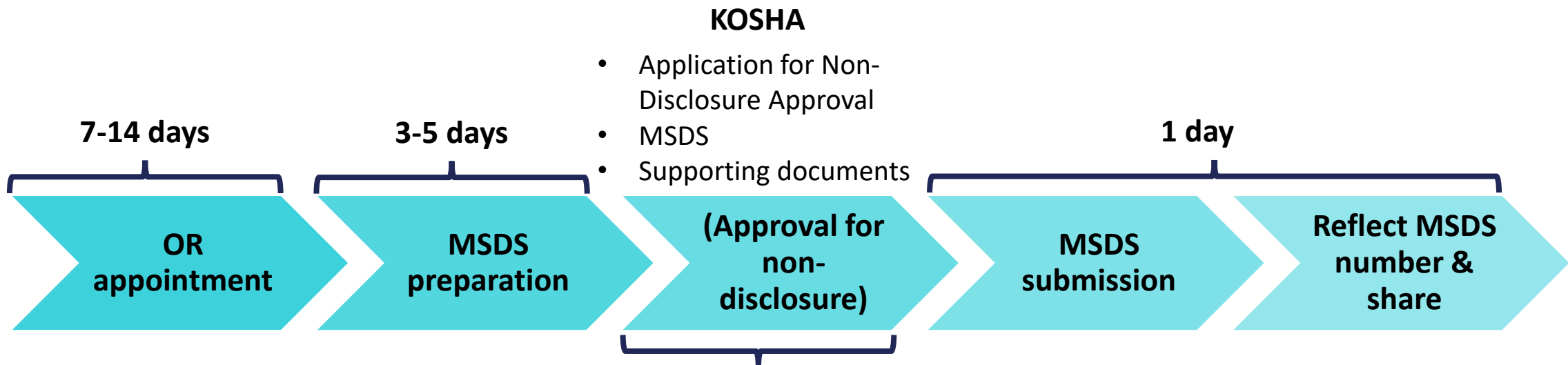
*Tonnage band: actual importing volume

New MSDS

- Newly imported after Jan 16th, 2021
- No grace period
- Need to submit MSDS prior to manufacture or import

MSDS preparation & submission

Process



- KOSHA**
- Application for Non-Disclosure Approval
 - MSDS
 - Supporting documents

Regional Employment and Labor Administration

- Application for OR appointment
- OR appointment letter
- A proof that OR is based in Korea

1 month + 10 days

KOSHA

- MSDS application
- MSDS
- Name and content of substances not classified under KOSHA*
- Appendix 62: Chemical substance confirmation document & Letter of confirmation*

OR appointment

■ 산업안전보건법 시행규칙 [별지 제68호서식]

국외제조사에 의한 선임서
 해임서

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

접수번호	접수일시	처리일	처리기간	7일
① 국외제조사	사업장명	제조(생산)국		
	담당자 성명 및 연락처	(전자우편 주소:)		
	주소	(전화번호:) (팩스번호:)		
② 선임(해임) 대상자	사업장명	사업자등록번호		
	성명(대표자)	담당자 성명 및 연락처	(이메일주소:)	
	주소	(전화번호:) (팩스번호:)		
③ 선임(해임) 분야	1. <input type="checkbox"/> 물질안전보건자료의 작성·제출(법 제110조제1항 또는 제3항) 2. <input type="checkbox"/> 화학물질의 명칭·함유량 또는 확인서류 제출(법 제110조제2항) 3. <input type="checkbox"/> 대체자료 기재, 유효기간 연장승인 또는 이의신청(법제112조제1항, 제5항, 제6항)			
④ 선임인 경우 선임 기간				
⑤ 해임인 경우 선임번호				

Information of a overseas manufacturer

OR information

Field

Period

OR number (if dismissal)

Confirmation

「산업안전보건법」 제113조제1항 및 동법 시행규칙 제166조제2항에 따라 국외제조자는 위와 같이 물질안전보건자료대상물질을 수입하는 자를 갈음하여 업무를 수행할 수 있는 자를 선임 해임 하였음을 신고합니다.

MSDS preparation (1)

- 16 sections

1. Identification of the product and company
2. Hazards identification
3. Information and composition on ingredients
4. First aid measures
5. Firefighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls and personal protection
9. Physical and chemical properties
10. Stability and Reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transportation information
15. Regulatory information
16. Other information

MSDS preparation (2)

1. Identification of the product and company
 2. Hazards identification
 3. Information and composition on ingredients
 4. First aid measures
 5. Firefighting measures
 6. Accidental release measures
 7. Handling and storage
 8. Exposure controls and personal protection
- Content can be a range of +/- 5%P

- Use the same product name or code that is used for the placards
- If the product is imported to Korea, the company information should be OR or contacts in Korea
- GHS pictograms
- Signal words
- Hazard statements (H codes)
- Precautionary statements (P codes)

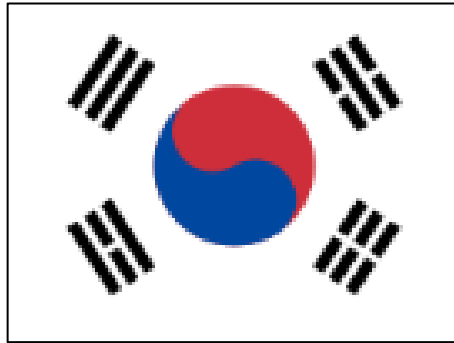
1.2.11. 흡인 유해성(aspiration hazard)

구분	1	2
GHS 그림문자		
RTDG 그림문자	요구되지 않음	요구되지 않음
신호어	위험	경고
유해·위험 문구	H304	H305
예방조치 문구	예방	없음
	대응	P301+ P310 P331
	저장	P405
	폐기	P501

MSDS preparation (3)

- 9. Physical and chemical properties
- 10. Stability and Reactivity
- 11. Toxicological information→
 - Sub-sections: exposure route, health hazards information
 - Can be merged into one sub-section
- 12. Ecological information
- 13. Disposal considerations
- 14. Transportation information
 - Korean regulations
- 15. Regulatory information→
 - Overseas regulations
- 16. Other information→
 - References of MSDS

MSDS preparation (4)



- In Korean language
 - Proper noun ex) product name, chemical substance name, overseas institute name, etc can be in English
- GLP (Good laboratory practice) & KOLAS (Korea Laboratory Accreditation Scheme) studies

Approval for non-disclosure

- To write the alternative information (alternative names and alternative content) in MSDS instead of information that are trade secrets
- Timeline: 1 month to get the result + 10 days if necessary
- The validity period of approval: 5 years from the date of approval

Alternative name

- Apply <Regulations on the Preparation of Data Protection Application and the Management of Protected Data, etc>


Alternative content

- If the content of the ingredient is 25% or more, +/- 20%P
- If the content of the ingredient is less than 25%, +/- 10%P

MSDS submission (1)



Chemical management by data



Create MSDS

private application

Non-disclosure application and approval according to Article 112 of the Occupational Safety and Health Act




Submit MSDS

Submission of material safety data sheet in accordance with Article 110 of the Occupational Safety and Health Act




Provide MSDS



information portal

MSDS submission (2)

New/ Existing MSDS

Tonnage band

Manufactured in Korea/ Imported

| 제품 제조·수입 시점 및 제조·수입량>

기제출 정보 불러오기

* 산업안전보건법 시행규칙 부칙 제9조, 제10조 및 제11조

신규 제품	기존 제품
<input type="radio"/> 2021년 1.16 또는 이후 제조·수입 화학물질 또는 제품	2021년 1.16 이전 제조·수입 화학물질 또는 제품 <input type="radio"/> 연간 제조·수입량 1,000톤 이상 <input checked="" type="radio"/> 연간 제조·수입량 100톤 이상 1,000톤 미만 <input type="radio"/> 연간 제조·수입량 10톤 이상 100톤 미만 <input type="radio"/> 연간 제조·수입량 1톤 이상 10톤 미만 <input type="radio"/> 연간 제조·수입량 1톤 미만
MSDS 공개 여부	<input type="radio"/> 공개 <input checked="" type="radio"/> 비공개
제조 구분	<input type="radio"/> 국내 제조제품 <input checked="" type="radio"/> 수입제품

MSDS submission (3)

OR appointment number

Product name

Use

*국외제조자의 선임자 제출 선임번호	<input type="text" value="선택"/> OR information										
*MSDS 번호	<input type="text"/> 중복검사	*MSDS 제개정일	<input type="text"/> 📅								
*제품명	<table border="1" style="width: 100%;"> <thead> <tr> <th>No</th> <th>*제품명</th> <th>제품코드</th> <th>추가</th> </tr> </thead> <tbody> <tr> <td>1</td> <td><input type="text"/></td> <td><input type="text"/></td> <td></td> </tr> </tbody> </table>			No	*제품명	제품코드	추가	1	<input type="text"/>	<input type="text"/>	
No	*제품명	제품코드	추가								
1	<input type="text"/>	<input type="text"/>									
*용도	<input type="text"/> 추가										
*제조사/공급자	회사명	<input type="text"/>	사업자등록번호	<input type="text"/>							
	주소	<input type="text"/> 주소검색									
	안전보건공단관리지사	-	고용노동부관리지사	-							
	전화번호	<input type="text" value="07046419856"/>	팩스번호	<input type="text" value="07079664641"/>							
	대표자	<input type="text"/>	전자우편주소	<input type="text" value="compliance@kr.gpcregulato"/>							
	업종	<input type="text" value="그 외 기타 전문, 과"/> 검색	근로자수	<input type="text" value="1"/>							

MSDS submission (4)

Composition of the product

Hazards information

MSDS attachment

구성성분

MSDS 제출 시 산업안전보건법 제110조에 따라 MSDS에 기재되지 않은 모든 성분을 제출해야 합니다.

산업안전보건법 시행령 별표35 과태료 부과기준

- 물질안전보건자료대상물질을 제조하거나 수입하려는 자가 화학물질의 명칭 및 함유량을 제출하지 않은 경우 : 1차 위반 100만원, 2차 위반 200만원, 3차 위반 500만원

MSDS제공기능을 통해 시스템 상 타사업장에 MSDS를 제공하는 경우, 제출 시 기재한 성분 중 미분류성분(MSDS 미기재)을 제외한 성분이 공유됩니다.

성분추가

함유량 입력은 범위값과 단일값을 중복으로 입력할 수 없습니다.

No	미분류 성분		입력선택	CAS 번호	*물질명	함유량(%)
	MSDS 미기재	MSDS 기재				범위
<div style="border: 1px solid black; padding: 5px;"> <p>제품 유해성·위험성 편집</p> </div>						

파일 첨부

*제품 MSDS	파일	크기
	<div style="border: 1px solid gray; padding: 2px;"> 1 Files / 200.0 MB / 200.0 MB(A) </div>	
<div style="display: inline-block; margin-right: 10px;">추가</div> <div>삭제</div>		

Appendix 62: Chemical substance confirmation document

■ 산업안전보건법 시행규칙 [별지 제62호서식] <개정 2022. 8. 18.>

화학물질 확인서류

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

접수번호	접수일시	처리일	처리기간	즉시
수입자	①선임인 [] 해당 - 신고번호() [] 비해당			
	사업장명	대표자	②업종	
	사업자등록번호	근로자 수		
	주소 (전자우편주소:)			
	전화번호	팩스번호		
③구분	[] 연구개발용 [] 비연구개발용			
④제품명	* 물질안전보건자료(MSDS) 상의 제품명과 동일한 제품명을 기재			
국외 제조사	사업장명(명칭)	제조국		
	주소 (전화번호:)			
⑤확인 내용	동 화학제품을 구성하는 화학물질(또는 단일 화학물질)에는 물질안전보건자료에 적힌 화학물질 외에는 「산업안전보건법」 제104조에 따른 분류기준에 해당하는 화학물질이 없음을 확인합니다.			

.....> OR information

.....> Classification

.....> Product name

.....> Overseas manufacturer

.....> Confirmation

Appendix 62: Chemical substance confirmation document

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 confirm that the ingredients, which are not listed on the SDS, are not classified hazardous according to the
classification criteria prescribed in the OSHA of Korea.

Name :(Signature or Seal)

Title :

Name of Department :

Company :

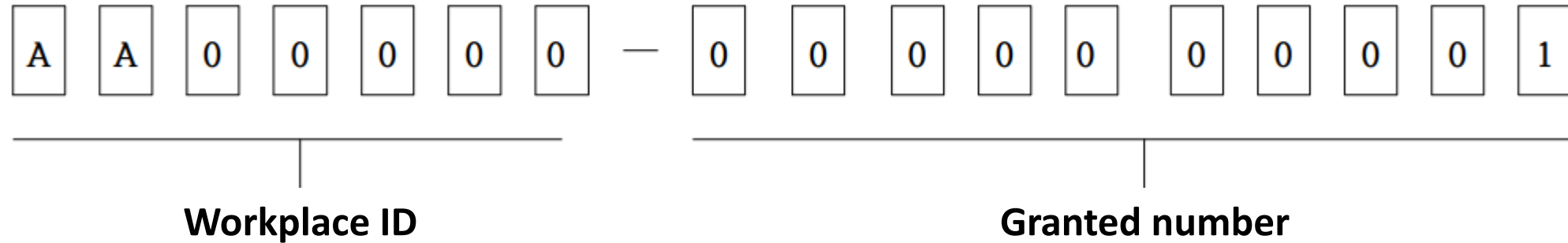
Address:

Tel :

Fax :

E-mail :

MSDS submission number



- Workplace ID: 2 digit alphabets + 5 digit numbers
 - AA – ZZ
 - 00000 - 99999
- Granted number: 10 digit numbers
 - 0000000001 - 9999999999

Update and resubmission

- If any of the following changes occur, need to update and resubmit MSDS reflecting the changes
 1. Product name
 2. Name and content of hazardous ingredients classified under KOSHA
 3. Health and environmental hazard
 4. Physical and chemical properties, etc

Administrative fines

MSDS

- Any of the following persons shall be punished by an administrative fine under 5 million KRW (4,000 USD):
 - who **fails** to submit MSDS or update MSDS
 - who **falsely submits a document** verifying that there is no chemical substance classified under KOSHA
 - who **fails to provide MSDS** to the importers

Approval for non-disclosure

- Any of the following persons shall be punished by an administrative fine under 5 million KRW (4,000 USD):
 - who provides alternative information for the names and content of chemical substances **without** obtaining approval
 - who applies for approval for non-disclosure or approval for extension prescribed by **falsely stating the reasons** for protecting the actual information on the grounds of trade secrets

Summary

- GHS Fourth revision edition
- MSDS with 16 sections
- Chemical manufacturers and importers & Only Representative (OR) appointed by overseas manufacturers
- MSDS preparation & submission, update & resubmission, transfer & provision
- 2-3 weeks from OR appointment to submission

Deadline	Tonnage band
Jan 16th, 2022	Over 1000 tpa
Jan 16th, 2023	100-1000 tpa
Jan 16th, 2024	10-100 tpa
Jan 16th, 2025	1-10 tpa
Jan 16th, 2026	Below 1 tpa

GPC services

Chemical Identification	Substance assessment for MSDS
MSDS	OR appointment for processing the MSDS of required substances
	MSDS submission via MSDS Portal
MSDS preparation	Analyze substance/mixture requirements
	Prepare MSDS
Communication	Representing and responding to the competent authority
	Representative (compliance) certificate to supply-chain
	Communication in supply chain
	Communication within the substance MSDS process
Regulatory Update (generic & substance - specific)	



Thank You!

“ *Your Seamless Extension in
Global Regulatory Compliance.* ”



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Scheelevägen 17,
223 63 Lund, Sweden



compliance@gpcregulatory.com



+ 46 (0) 46 211 46 15



www.gpcgateway.com



GPC

Global Product Compliance