Evaluation of the completeness and accuracy of 42 safety data sheets (SDSs) of chemical substances, 2019





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ABSTRACT

Objective: This study aimed to evaluate the completeness and accuracy of information on the SDS that has been reported to the SIINAS (Indonesian Industrial Information System).

Methods: The SDSs of 42 chemical substances were evaluated using a checklist that includes (1) the completeness check which refers to the Indonesian Regulation and (2) the accuracy check which refers to the European Chemicals Agency (ECHA) - info card and the National Institute of Technology and Evaluation (NITE) of Japan – Chemical Risk Information Platform (CHRIP).

Result: The evaluation on the completeness check showed that all SDS provides complete information on the hazard identification (SDS element 2), yet none of SDS provides complete toxicological information (SDS element 11). On the other hand, the evaluation on the SDS accuracy found that 21 SDSs were accurate based on ECHA-Infocard and 4 SDSs were accurate based on NITE-CHRIP.

Conclusion: This study shows that there are weaknesses in the completeness and accuracy of SDS available in Indonesia. Strengthening the knowledge on GHS and available resources as reference for SDS production is ought to be improved.

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Introduction

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) is implemented globally to standardise and harmonise the criteria of hazard classification and communication on the label and safety data sheets (SDSs) of chemicals.¹ The GHS was originally developed on the basis of the international mandate, known as the 'Earth Summit' in 1992, which stated that a globally harmonised system related to the hazard classification and labelling of chemicals, including material safety data sheets and easily understandable symbols, should be available, if feasible, by the year 2000.² The GHS was officially adopted in December 2002 by the UN GHS Sub-Committee, which was subsequently endorsed by the UNCETDG and the UN Economic and Social Council in July $2003.^3$

Indonesia has adopted the GHS since December 31, 2010 through the enactment of policies that applied for chemical substances that are produced domestically and imported ones.⁴ Every chemical producer or importer is obligated to submit a report to the Directorate General of Industrial Regional Development pertaining to the implementation of the GHS on labels and SDSs for each product through the National Industrial Information System (SIINas) portal.⁵ Verification is conducted to check the completeness and validity of the documents that have been reported.⁶ However, the evaluation of the completeness and accuracy of information on the SDS has not been performed. Thus, this study evaluated the com-

pleteness and accuracy of the SDS that has been reported to the MoI of Indonesia.

Methods

Obtaining the SDSs

42 SDS were obtained from SIINAS. Indonesian Industrial Information System, through a non-probability sampling technique.

Evaluating the SDSs

The SDSs were evaluated using the checklist that includes the completeness check, which refers to the Regulation of the MoI of Indonesia number 23/M-IND/PER/4/2013 and the Director General Manufacturing Industry Base Regulation number 04/BIM/PER/1/2014,^{1,7} and the accuracy check, which refers to the hazard classification based on the GHS listed in the European Chemicals Agency (ECHA) - Infocard and the National Institute of Technology and Evaluation (NITE) of Japan - Chemical Risk Information Platform (CHRIP).8,9

An evaluation on the completeness check was conducted on all elements of the SDS to determine whether the information has complied with the provisions of the Indonesian Regulation. While, an evaluation on the accuracy check was limited to only element 2 and element 3 of the SDS to determine whether the information is in accordance with the hazard classification based on the GHS listed in ECHA-Infocard and NITE-CHRIP. The scoring criteria of the completeness and accuracy check of the SDS used were based on the modified Laura et al. and Klimisch et al. criteria (shown in Table 1).10,11

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Table 1

Scoring criteria of the completeness and accuracy check.

Score	Criteria
1	Complete: All information provided. Accurate: All information is in accordance with the hazard classification in ECHA-Infocard and NITE-CHRIP.
0	Incomplete: There is one or more information that is not provided. Inaccurate: There is one or more information that does not in accordance with the hazard classification in ECHA-Infocard and NITE-CHRIP.

Source: Modified by Hodson et al.¹⁰ and Klimisch et al.¹¹

Table 2

Category reliability of SDSs.

Total score	Category	
=80 <80	Reliable Unreliable	

Source: Modified by Hodson et al.¹⁰ and Klimisch et al.¹¹

The total score was used to determine the completeness and accuracy of the SDS. The total score can be categorised as follows:

- 1. If the total score of the completeness check is 75, then the SDS is categorised as complete.
- 2. If the total score of the completeness check is less than 75, then the SDS is categorised as incomplete.
- 3. If the total score of the accuracy check is 5, then the SDS is categorised as accurate.
- 4. If the score of the accuracy check is less than 5, then the SDS is categorised as inaccurate.

The scores obtained from the completeness and accuracy check are summed to determine whether the SDS is reliable or unreliable as shown in Table 2.

Ethical considerations

Ethical approval for this study was obtained from the Research and Community Engagement Ethical Committee, Faculty of Public Health, Universitas Indonesia.

Result

The results of the completeness check showed that there is no SDS reached 100% of the completeness criteria. Among the 16 elements of the SDS, as shown in Table 3, only element 2 (i.e., hazard identification) complied with the requirement. The sub-elements in element 2 consisted of the GHS classification of the chemical substance, signal words, hazard statements, precautionary statements and hazard pictograms. The most incomplete element of the SDS was element 11 (i.e., toxicological information) found in sub-element 3, which is related to the route of exposure, and sub-element 3, which is related to the symptoms of the physical, chemical and toxicological properties of chemicals.

While, the results of the accuracy check showed that there are 21 SDSs categorised as accurate based on ECHA-Infocard and 4 SDSs categorised as accurate based on NITE-CHRIP. As shown in Table 4, only element 3 reached 100% of the accuracy criteria. In element 2 (i.e., hazard classification), 24 SDSs were categorised as accurate based on ECHA-Infocard and 4 SDSs were categorised as accurate based on NITE-CHRIP. Regarding the completeness and accuracy check of the information, as shown in Table 5, all SDSs were categorised as unreliable.

Discussion

Completeness check of information on the SDSs

The completeness check showed that, among 75 sub-elements evaluated, 18 sub-elements showed a proportion value that was 100% complete. Thus, the relevant information on the 18 sub-elements of the SDS was provided in all 42 SDSs that had been evaluated. Moreover, element 2 (i.e., hazard identification) had a 100% complete proportion value for all of its sub-elements.

Further analysis showed that in element 11 (i.e., toxicological information), sub-element 2, which contains the information of the exposure route, and sub-element 3, which contains the information of the symptoms related to the physical, chemical and toxicological properties of chemicals, had the lowest total value of 0. This finding indicates that there is no SDS that provides the necessary information on this sub-element.

Based on the results, many factors could cause chemical industries to withhold the information needed for each element in the SDS such as:

- 1. Lack of workers knowledge regarding the format of the SDS in accordance with the provisions of the Indonesian Regulation.
- 2. Unavailability of information that can be used as reference in the preparation of the SDS.
- 3. Lack of training for workers on the preparation of the SDS in accordance with the format stipulated in the Indonesian Regulation.

Thus, the evaluation of the completeness of the SDS showed that all 42 SDSs (100%) were categorised as incomplete. Therefore, none of the SDS complied with the provisions in the Regulation of the MoI of Indonesia number 23/M-IND/PER/4/2013 and the Director General Manufacturing Industry Base Regulation number 04/BIM/PER/1/2014.

Accuracy check of information on the SDSs

The evaluation regarding the accuracy of information on the SDS showed that, among the five evaluated sub-elements, one subelement related to the CAS number in element 3 of the SDS had a proportion that was 100% accurate according to the hazard classification based on the GHS listed in ECHA-Infocard and NITE-CHRIP.

Further analysis showed that in element 2 (i.e. hazard identification), no sub-elements were 100% accurate. Thus, some SDSs did not provide information in accordance with the hazard classification of chemicals based on the GHS listed in ECHA-Infocard and NITE-CHRIP.

According to the results, many factors can cause chemical industries to withhold information such as:

- 1. Lack of competencies of workers from related chemical industries regarding the hazard classification of chemicals based on GHS.
- 2. Lack of information regarding databases that can be used as reference in order to classify chemical hazards based on the GHS.
- 3. Lack of training for workers from related chemical industries regarding the hazard classification of chemicals based on the GHS.

Thus, based on ECHA-Infocard, the accuracy check showed the same proportion, 21 SDSs were categorised as accurate and 21 SDSs were categorised as inaccurate. These findings showed that only half of the SDSs that were used as samples provided the necessary

Table 3Distribution of the completeness check.

Element	Sub-element	Complete		Incomplete		
		N	%	N	%	
1	1	42	100	0	0	
	2	41	97.62	1	2.38	
	3	42	100	0	0	
2	4	41	100	0	0	
	2	42	100	0	0	
	3	42	100	0	0	
	4 5	42	100	0	0	
3	1	42	100	0	0	
	2	31	73.81	11	26.19	
	3	42	100	0	0	
4	1	42	100	40	0	
	2	42	100	0	0	
	3	41	97.62	1	2.38	
	4 5	42	21.43	33	0 78.57	
	6	10	23.81	32	76.19	
5	1	42	100	0	0	
	2	16	38.10	26	61.90 7.14	
	4	42	100	0	0	
6	1	40	95.24	2	4.76	
	2	41	97.62	1	2.38	
7	3	41	97.62	1	2.38	
	2	38	90.48	4	9.52	
	3	41	97.62	1	2.38	
8	1	41	97.62 52.38	1	2.38	
	3	42	100	0	0	
9	1	42	100	0	0	
	2	40	95.24	2	4.76	
	3 4	15	42.86	27	64.29 57.14	
	5	40	95.24	2	4.76	
	6	42	100	0	0	
	/ 8	38 40	90.48 95.24	4	9.52 4.76	
	9	31	73.81	11	26.19	
	10	40	95.24	2	4.76	
	11	35	83.33	7	16.67	
	12	39	92.86	3	7.14	
	14	41	97.62	1	2.38	
	15	22	52.38	20	47.62	
	18	2	90.48 4.76	4	9.52	
	18	20	47.62	22	52.38	
10	1	42	100	0	0	
	2 3	40	88.10 95.24	5 2	4.76	
	4	38	90.48	4	9.52	
11	5	37	88.10	5	11.90	
11	1	17	40.48	25 42	59.52 100	
	3	0	0	42	100	
	4	26	61.90	16	38.10	
12	5	36 41	85.71	6	14.29	
12	2	36	85.71	6	14.29	
	3	36	85.71	6	14.29	
12	4	23	54.76	19	45.24	
13	1	41 41	97.62	1	2.38	
- •	2	23	54.76	19	45.24	
	3	41	97.62	1	2.38	
	4	17	40.48	25	59.52	
15	5	41	97.62	1	2.38	
16	1	10	23.81	32	76.19	
	2	39	92.86	3	7.14	
	3	32	76.19 38.10	10	23.81	
	Ŧ	10	50.10	20	01.50	

Table 4

Distribution of the accuracy check.

Element	Sub-element		ECHA – EU				NITE – Japan			
		Acc	Accurate		Accurate Inaccurate		Accurate		Inaccurate	
		N	%	N	%	N	%	N	%	
2	1	24	57.1	18	42.9	4	9.52	38	90.48	
	2	34	81	8	19	28	66.67	14	33.33	
	3	26	61.9	16	38.1	6	14.29	36	85.71	
	4	31	73.8	11	26.2	13	30.95	29	69.05	
3	1	42	100	0	0	42	100	0	0	

Source: Primary Data (2019).

Table 5

Distribution of the reliability of the SDSs.

Category	Score	Ν	%
Reliable	=80	0	0
Unreliable	<80	42	100

Source: Primary Data (2019).

information in accordance with the hazard classification based on the GHS as listed by ECHA.

While, based on NITE-CHRIP, only 4 SDSs were categorised as accurate and 38 SDSs as inaccurate. As shown by the results, a significant difference was found in the value of accuracy between ECHA-Infocard and NITE-CHRIP. Among the 42 SDSs, the majority tended to follow the hazard classifications listed by ECHA compared with NITE. The reason is that Indonesia still refers to the fourth edition of the UN GHS, whereas NITE-CHRIP implements the sixth edition of the UN GHS.^{9,12}

Conclusion

This study revealed some weaknesses of the 42 SDSs that have been reported to the SIINAS. For the completeness test, all 42 SDSs were categorised as incomplete. While, for the accuracy test, 21 SDSs were found to be accurate according to ECHA-Infocard, and only 4 SDSs were found to be accurate according to NITE-CHRIP. Efforts on the improvement of SDS reliability in Indonesia need to be in place.

Conflicts of interest

The authors declare no conflict of interest.

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