Risk Management Option Analysis Conclusion Document

Substance Name: Indium tin oxide (ITO)

EC Number: 610-589-1

CAS Number: 50926-11-9

Authority: RIVM on behalf of the NL-CA

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Indium tin oxide is not yet registered under REACH. There is no EU legislation nor any ongoing regulatory initiatives for indium tin oxide. The novel application of indium tin oxide (ITO), specially the use of the nanoform are a point of concern with regard to the exposure of workers in indium processing facilities.

2. CONCLUSION OF RMOA

Indium tin oxide (ITO) was selected on the basis of a publication of occupational health effects observed occurring in plants where workers are being exposed to ITO, especially in its nano-form. Awaiting possible further risk management measures depending on the actual registration of ITO in 2018, the NL-CA advices to contact those facilities for which is known they may work with indium tin oxide to make sure they are aware of the possible severe health effects of exposure.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	X
No action needed at this time	

3. POSSIBLE USES

ITO is not yet registered. Consequently, an overview of uses is not yet available from the registration dossier. Uses extracted from open literature include the following:

Table: Uses

	Use(s)
Uses as intermediate	
Formulation	Indium tin oxide may be formulated as alloy of Indium and tin oxide. This is currently not reflected by the preregistration under REACH that indicated ITO as multi-constituent substance.
Uses at industrial sites	Indium tin oxide is used to produce ITO powders, which are used in the film deposition. Exposure to workers could also occur at recycling of ITO containing articles. Indium tin oxide is used as a coating in consumer products like cell phones, solar panels, LCDs, flat panel displays etc.
Uses by professional workers	Indium tin oxide is used to produce ITO powders, which are used in the film deposition. Exposure to workers could also occur at recycling of ITO containing articles. Indium tin oxide is used as a coating in consumer products like cell phones, solar panels, LCDs, flat panel displays etc.

Consumer Uses	Indium tin oxide is not used by consumers as such.
Article service life	

Additional information extracted from the New and Emerging Risks project of the RIVM hints that ITO may be used in a number of companies and universities located in the Netherlands:

- Philips (coating on light bulbs)
- Philips research (production organic LEDs)
- NXP (Chip-on-glass LCD Driver Technology)
- TUE (Atomic Layer Deposition for nanowire devices)
- Radboud University (ITO coated glass slides as a substrate for cell culture)
- Solliance Solar Research (Thin film PV production)
- Smit Ovens, Thermal solutions (Production of CIGS solar panels)
- OM&T B.V. (Production of optical discs and photovoltaic cells and modules)

And possibly by:

- Solland Solar Cells (Solar panels)
- Philips – (production LCD screens)

It is suspected that due to the massive industrial growth of LCD panels the demand of ITO is growing. This makes the recovery of indium from manufactured materials and waste of great commercial interest.

Three European importers were asked for further information on uses. No information was received.

Greatest potential for exposure is expected as a result of industrial use. This exposure is expected to become more prevalent as the use of ITO is expected to increase over the upcoming years because the market demand for its applications is expected to further increase. The primary routes of exposure, as derived from documented human cases, are inhalation, ingestion, and eye and skin contact. Workers handling powdered ITO or engaged in machining, polishing or wet grinding of ITO targets after compaction may inhale ITO. The majority of worlds' ITO is utilized in the east of Asia (Japan, Korea), a smaller part is used in the US.

4. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

It is anticipated that due to the growing market of solar panels and LCD screens applications, the use of indium in the form of ITO will increase in the following years. The inflammatory and genotoxic activities of ITO, described in human and animal studies, indicate that a control of exposure in industrial settings is needed. At present, communication of these health hazards is not organized and no harmonised or self classification under CLP reflects the hazards observed in the working population.

Table: SVHC Roadmap 2020 criteria

	Yes	No
a) Art 57 criteria fulfilled?	maybe	
b) Registrations in accordance with Article 10?		n.a.*

c) Registrations include uses within scope of authorisation?	n.a.*	
d) Known uses not already regulated by specific EU legislation that provides a pressure for substitution?	x	

** substance is not yet registered under REACH*

4.1 Identification, assessment and conclusion of risk management options

The effects observed in humans and in vivo in testing animals suggest severe health effects are possible upon exposure to Indium tin oxide as inhalable dust. Exposure to indium tin oxide may lead to pulmonary alveolar proteinosis which eventually may lead to lung fibrosis, emphysema and potentially death. Epidemiological studies suggest that these effects are not acute, but develop over time and may not be reversible, possibly depending on the dose of exposure. Occupational exposure limits have been recommended by NIOSH (0.1 mg/m^3) and the Japan Society (0.0003 mg/m^3). However, based on the current data it is uncertain if a threshold of effect can be established. The severity of the effects demonstrated in humans does suggest that this substance may be of equivalent level of concern to CMR and hence may meet article 57(f) of REACH.
At present, the substance is preregistered under REACH. As a consequence, information on production and use in the EU is limited. It is expected that registration under REACH in 2018 may shed further light on production and uses in the EU and the hazard profile of this substance. As none of the occupational health cases describe European sites (but Asian or American industrial sites), there is no information suggesting a risk for the European population that demands direct action. Hence, concluding that a restriction on the production and use of this substance is needed, may be premature.
Evaluating the possibility to propose harmonized classification under CLP would be a logical first step towards any further regulatory measures. Given the effects observed in humans, harmonised classification as STOT RE 1 may be possible.

Depending on the classification, the Authorisation route could be considered. If the substance becomes classified as STOT RE 1, an equivalent level of concern may be motivated under article 57(f). The amount of information available on worker cases suggests enough information is available to illustrate the possible severity of the effect in humans. Alternatively, and irrespective of harmonised classification, Restriction could be considered, based on the similar set of human cases currently available in literature. However, the effectiveness of any measure under REACH will depend on the actual production and use characteristics and whether these take place within or outside Europe. Furthermore, the NL-CA has some reservation with regard to the substance identity of ITO. It is preregistered as a multi-constituent substance, but may in fact be an alloy and hence a mixture. When ITO is a mixture, the option of harmonised classification will change and also the possible Authorisation route may change. It is therefore concluded to await the actual registration of indium tin oxide in 2018 before any risk management options are further concluded on, including Compliance check. The NL-CA is of the intention to revisit this RMOA 2018/2019 once Indium tin oxide is registered.

Awaiting possible further risk management measures depending on the actual registration of ITO in 2018, the NL-CA advices to contact those facilities for which is known they may work with indium tin oxide to make sure they are aware of the possible severe health effects of exposure.