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## WATCH COMMITTEE

### Isocyanic acid and other monoisocyanates: potential for respiratory irritation and sensitisation

#### Issue

1. Risk management approaches to isocyanic acid and other monoisocyanates.

#### Timing Considerations

2. Routine

#### Recommendation

3. WATCH is invited to consider the issues noted in this cover paper and to respond to the actions in paragraph 13.

#### Background

4. According to the criteria of the EU hazard classification system for dangerous substances, any isocyanate (monoisocyanates or diisocyanate) should be classified for the hazardous property of respiratory sensitisation (risk phrase: *May cause sensitisation by inhalation* R42), unless there is evidence that the particular substance does not cause respiratory hypersensitivity. The relatively strict risk management provisions of Annex 3 of the COSHH Regulations (2002), which take account of the seriousness of respiratory sensitisation, apply to all substances assigned R42 (or R42/43). A number of isocyanates, including some monoisocyanates as well as diisocyanates, are specifically included in Annex I of EU Directive 67/548/EEC with a harmonised hazard classification (i.e. a classification agreed at the EU level) that includes the risk phrases R42 or R42/43; all are also classified as *Irritating to the respiratory system* (R37) or as *corrosive* (*Causes burns* R34 or *Causes severe burns* R35), the corrosive classification subsuming the assumption that the substance can cause respiratory tract irritation. These substances are listed in the attached Annex 1.

5. GB Workplace Exposure Limits (WELs) of 0.02 mg.m<sup>-3</sup> (8 h TWA) and 0.07 mg.m<sup>-3</sup> (STEL) (as –NCO) and a ‘Sen’ notation, apply to isocyanates under a generic entry in EH40/2005 for ‘Isocyanates, all’. This WEL was set mainly on the basis of data relating specifically to toluene diisocyanate (TDI) showing that this substance can cause respiratory tract sensitisation and irritation (HSE, 1993). An assumption was made that this toxicity was due to the isocyanate group and that all other isocyanates may also be respiratory sensitisers. It should be noted that the assumption that respiratory sensitisation could be induced by all isocyanates was not made by the Scientific Committee on Occupational Exposure Limits (SCOEL) in their recommendation for an occupational exposure limit for methyl isocyanate (MIC, CAS no. 624-83-9) (SCOEL, 2005). SCOEL considered that MIC is not a respiratory sensitiser because of the absence of direct supporting evidence in humans and regarded eye/respiratory tract/mucous membrane irritation as the critical adverse health effect. A limit of 0.5 ppm (1.2 mg.m<sup>-3</sup>, a STEL) was proposed to protect against

these effects. Coincidentally, this limit expressed in terms of –NCO is 0.09 mg.m<sup>-3</sup>, which is very similar to the WEL STEL for isocyanates.

6. It is also noted that the ‘default’ assumption of the EU hazard classification and GB WEL systems that all isocyanates have the potential to cause respiratory sensitisation is not in agreement with the strategy for evaluating respiratory sensitisation data in the Technical Guidance Document (TGD) on information requirements for REACH (EC 2007). The TGD proposes that, in the absence of specific health effects data, only **diisocyanates** that also meet the criteria for classification for skin sensitisation are presumed to be respiratory sensitisers.

7. Diisocyanates are the predominant form of isocyanate used in workplaces. However, it is known that low molecular weight isocyanates such as MIC, isocyanic acid (ICA, CAS no. 75-13-8) and other monoisocyanates (e.g. ethyl, butyl, hexyl, phenyl etc) can be generated in a number of industrial processes.

8. It is firmly established that diisocyanates can cause respiratory tract irritation and have the potential to induce respiratory sensitisation leading to asthma, but there is no established consensus view on the health effects associated with occupational exposure to monoisocyanates.

## **Argument**

9. Several challenges (including the SCOEL MIC assessment and REACH TGD) to the notion of treating all isocyanates similarly, in hazard and risk management terms, have prompted this review of the monoisocyanates. HSE has assessed the current knowledge on the effects of the monoisocyanates on respiratory health (Annex 2). Information on their occupational use and exposure is outlined, and the available toxicity data on MIC, ICA and other monoisocyanates, including information on immunological and inflammatory responses in animal models and humans, is considered. This paper has an emphasis on ICA because this substance was possibly detected recently, at significant concentrations, in the air at a GB factory.

## **Link to HSC Strategy**

10. This is a generic, “business enabling” issue of relevance to HSE’s substance-specific assessments within both Statutory work and the Disease Reduction Programme.

## **Consultation**

11. No wider consultation on the content of this cover paper beyond HSE has been undertaken at this stage.

## **European Context**

12. There are no specific links to EU procedures or activities.

## **Action**

13. WATCH is asked to consider the evidence presented in this document and to take a position on:

- (i) the potential for isocyanic acid and other monoisocyanates to cause respiratory sensitisation and irritation in the workplace

- (ii) whether it is appropriate to apply an equally stringent regulatory regime to all isocyanates (monoisocyanates and diisocyanates), based on the presumption that all isocyanates have the potential to cause respiratory sensitisation and are potent respiratory tract irritants

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**Attachments**

Annex 1 Isocyanates included in Annex 1 of Directive 67/548/EEC (list of harmonised classifications and labelling for substances or groups of substances, which are legally binding within the EU).

Annex 2 Assessment of the potential of isocyanic acid and other mono-isocyanates to cause respiratory irritation and sensitisation

**References**

EC (2007) Technical Guidance Document to Industry on the information requirements for REACH. Part 2, page 225. Available at:  
[http://ecb.jrc.it/documents/REACH/RIP\\_FINAL\\_REPORTS/RIP\\_3.3\\_INFO\\_REQUIREMENTS/FINAL\\_DRAFT\\_GUIDANCE/RIP3.3\\_TGD\\_FINAL\\_2007-05-04\\_Part2.pdf](http://ecb.jrc.it/documents/REACH/RIP_FINAL_REPORTS/RIP_3.3_INFO_REQUIREMENTS/FINAL_DRAFT_GUIDANCE/RIP3.3_TGD_FINAL_2007-05-04_Part2.pdf)

HSE (1993) Isocyanates. EH64 summary criteria for occupational exposure limits. Summary number C18. HSE Books, Sudbury, United Kingdom.