

RioTinto

RCS Overview for Iron Pellets

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Impact study possible revision Carcinogens Directive

Proposed OELs for RCS:

0.05 mg/m³ - 0.1 mg/m³ - 0.2 mg/m³

Appointed contractors led by the IOM (J. Cherry)

Final report expected in June 2010

Questionnaire sent to all stakeholders concerned by RCS exposure

(and also all the other substances involved) on 16 September '09

Replies expected end of October '09

SHEcan Project - questionnaire

Section 1: Manufacture use, releases and exposure

Are you aware of any work to undertake a risk assessment for respirable crystalline silica, either a voluntary assessment or a more formal regulatory assessment?
If yes, can you provide brief details

NEPSI answer: risk assessment of the SDA

For regulatory assessment, we will remind them of the UK impact assessment.

SHEcan Project - questionnaire

Do you have information on industries where there is exposure to respirable crystalline silica? If yes, could you provide information on:

a) the range of processes/sectors (e.g. quarrying, construction etc), including the quantity (mass) of this parent materials produced/processed, ideally by country or region in the EU.

Production figures from IMA survey.

b) information on the number of people exposed, even approximate data, ideally by country or region within the EU. NEPSI answer.

c) what risk management measures are associated to these uses, including personal protective equipment. NEPSI answer.

d) any available personal occupational exposure data or general views about the likely exposure levels. **IMA DMP**

e) are there certain tasks/jobs that are likely to have higher occupational exposure than others (what approximate proportion of the total exposed population are involved in this task/job)? **IMA DMP**

f) what proportion of workplaces do you consider comply with an exposure limit of 0.05 mg/m³ or 0.1 mg/m³ (although note this is not necessarily part of the proposals from the EU)? **IMA DMP**

SHEcan Project - questionnaire

Section 2: Exposure of workers and health

3. What is the approximate number of workers at each process/sectors (e.g. quarrying, construction etc), by country within the EU, who may be exposed? NEPSI answer

4. Is there any available exposure data you can share with us or could you give a general view about the levels of exposure, and whether exposure/levels patterns have changed in recent years.

IMA DMP

5. Are there any examples of “best practice” guidance for situations where people are exposed to respirable crystalline silica (other than the NEPSI guidance, of which we are aware)? If so, please provide details.

We make a list and circulate it for completion

6. If respirable crystalline silica was included within the scope of the Carcinogens Directive then how would you expect employers to comply with the requirements? Also, how might this vary across Member States within the EU?

We draft a general answer and circulate it for approval/comments

SHEcan Project - questionnaire

Section 3: Financial/market information

7. What is the market value for the industries where there is exposure to respirable crystalline silica? What are the likely broad trends in production/use in the future and is the use pattern likely to change in the future?

For IMA, Total Turnover figure from IMA survey

For DU industries: we ask clarification to IOM

In the future, “40% of sales at risk”

8. If the substance was included in the Carcinogens Directive, what do you estimate the associated costs of compliance with OEL 0.05 or 0.1 mg/m³ to be?

Please be as specific as possible, breaking down costs into capital expenditure, ongoing and other costs associated with defined equipment or actions, by sector/country.

We use the UK study and send it to contacts in each MS to confirm if can be used for their country.

9. In broad terms, what impact might the options (e.g. setting an OEL) have on the conduct of the business (e.g. possible impact on R&D, employment, investment, relocation, competitiveness)?

We propose an answer and circulate it for comments.

SHEcan Project - questionnaire

10. In the event that downstream users could not comply with an OEL or other requirements of the Carcinogens Directive, are there any alternative substances or approaches that could be applied? How does the performance (efficacy, cost, health/environmental risks) of these substitutes compare to that of materials containing crystalline silica?

We draft a general sentence “continuous CS...” from SDA and GPG”. + All minerals contain amounts of quartz...

11. What might be the environmental impact of complying with and OEL or other requirement following any decision to include respirable crystalline silica in the Carcinogens Directive (e.g. increase / decrease in energy consumption, change in emissions to air, increase / decrease in waste)?

We draft an answer and circulate it for comments.

General statement: consequences of carcinogens directive and of OELs should be considered separately.

For IMA, an OEL is not such an issue but being in the carcinogens directive would have tremendous consequences on the IM business (Chemicals at work Directive preferable)

Classification and Labelling of Respirable Crystalline Silica

The Proposal

- A classification scenario leading to a common entry in the Inventory
- Accompanied by a series of measures guaranteeing a high level of
 - Awareness of the hazard & the risks
 - Protection of workers & consumers health
- An approach which can meet authorities & stakeholders expectations while uniting industry partners
- A mechanism of regular evaluation of this decision taking into account e.g. SDA implementation and further scientific research progress
- Not the only possible classification scenario, but a serious proposal to be discussed first with authorities (DG EMPL, ECHA, DG ENVI)

The Classification

- **Classify Quartz, respirable – Cristobalite, respirable**
(CLP takes account of form hazard)
- **Classify STOT 1 RE** for silicosis

STOT 1 - Specific Target Organ Systemic Toxicant (repeated exposure) Category 1



Danger. Causes damage to lungs through prolonged or repeated exposure via inhalation

Substances that have produced significant toxicity in humans, or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following repeated exposure

Concentration \geq 10% → STOT 1
1.0% \leq concentration < 10% STOT 2

Accompanying effective measures

An exhaustive documentation provided into the supply chain:

- **Classification labelling and packaging recommendation**
- Summary of the **hazard assessment** for RCS
- **Description of identified uses** and elements of a CSR,
- Recommendations for updated **Safety Data Sheet (SDS)**
- **SWeRF method**, a scientific and reliable method developed by industry to measure respirable fraction in bulk materials. SWeRF_{CS} defines RCS. To be submitted for standardisation
- Reinforced communication to professional users, based on the Good Practice Guide task sheets **to be complemented by task sheets on construction works**
- **Wide Communication on this C&L to other M/I** through direct contacts with the main stakeholders & a dedicated website

Accompanying effective measures

A complete argumentation documenting the grounds on which we rely on to conclude on a classification STOT RE 1

- 1) Health effects only appear at the workplace, not in the general environment**
- 2) Only the respirable fraction is dangerous**
- 3) Increased risk of lung cancer is not observed in all industrial circumstances studied**
- 4) Any cancer effect is indirect/secondary**

1. Classification labelling & packaging recommendation

DRAFT Label for respirable quartz or respirable cristobalite:

CLP Reg: Table 3.9.5: Label elements for *specific target organ toxicity after repeated exposure (STOT RE 1)*

GHS Pictogram:



Class : Category 1

Signal word: Danger

Hazard Statement H372: Causes damage to organs (state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)

Precautionary Statement Prevention:

P260: do not breathe dust (manufacturer/supplier to specify applicable conditions)

P264: wash ... thoroughly after handling (Manufacturer/supplier to specify parts of the body to be washed after handling)

P270: Do not eat, drink or smoke when using this product

Precautionary Statement Response:

P314: Get medical advice/attention

Precautionary Statement Disposal:

P501: Dispose of contents/containers to ... in accordance with local/regional/national/international regulation (to be specified)

2. Summary of the hazard assessment for RCS

Deadline: 1 April 2010

- Obtain final documents from epi and tox experts
- Integrate them in IUCLID 5
- Draft summary fitting the STOT 1 classification
- Share it with all contributors

Draft Conclusions of the Epi-Group

1. Health effect evidence due to silica is linked to RCS
2. None of the studies reviewed has all of the characteristics of an ideal epi-study (large cohort, robust quantitative estimates of RCS exposure for each study individual and of co-exposures, potential confounders such as smoking and concomitant diseases such as silicosis)
3. Silicosis is the only non-malignant health effect due to RCS which is proved to be specific and clearly linked to RCS
4. Cancer evidence is limited to lung cancer occurrence, evidence for other malignant health endpoints is limited and not thoroughly investigated
5. Lung cancer risk is convincingly demonstrated only under high (≥ 6 mg/m³) cumulative exposures to RCS (Steenland et al. 2001 “silica is a weak lung cancer carcinogen”, Pukkala et al. 2005). There is no consistent dose-responses evidence
6. Excess lung cancer risks is restricted to silicotics (Erren et al. 2008)
7. Epidemiological studies and animal experiments showed dose-response relationships between RCS and silicosis (Mannetje 2001, Muhle 1991)

Draft Conclusions of the Tox-Group

1. There is little consistent comparison between quartz species experimental toxicity
2. Studies comparing different species give no evidence that one of these species is more active than others
3. All studies however indicate that the activity is very much determined by the surface and this can easily be passivated or activated with physical and/or chemical treatments.
4. RCS do not enter the nucleus of the cells
5. In vivo, no quartz particles are found in epithelial cells
6. In vivo, cytotoxicity is through inflammatory processes
7. In vitro, there is no consistent evidence of a direct genotoxic effect in plausible biological conditions

3. Elements of the Chemical Safety Report (CSR)

- Description of identified uses

“Guidance on safe use”

Scope: not defined yet

- Derivation of DNELs (or OELs)

Deadline: 1 April 2010

4. Update Safety Data Sheet (SDS)

- Develop harmonised templates

5. SWeRF method

- Prepare the standardisation
Contact CEN

20 months after start of procedure

- Communicate the SWeRF to all IMA Members

Proposed action:

Draft a memo to technical committees explaining:

- 1) Measure quartz content of your products
- 2) If $Q > 1\%$ (**to correct**): make $SWeRF_{cs}$ sedimentation tests and calculation to see your RCS content. Give instructions how to make the tests (= companies' projects)
- 3) Anonymous results communicated to the TC and the Metrology WG to enrich the database

To be done as soon as possible to check level of concern

Co-ordination: I. Pensis + other industry experts (+ FL)

Responsible WG: IMA Metrology WG

6. Communication to professional users

- Good Practice Guide task sheets to be complemented for construction works

7. Complete argumentation

- Document each point of the argumentation

Deadline: 1 April 2010

8. Communication

- **Within IMA & to other M/I - Last quarter 2009**
 - Draw the list of target audiences
 - Send them the memo
 - Organise meetings

- **Towards selected authorities**
only when dossier is fully completed: by April 2010

- **Dedicated website**

Targeted audiences

IMA Sections

- IMA Board & AGM ✓
- CCA
- EBA
- EUBA
- EuLA ✓
- EUROTALC
- EUROFEL
- EUROSIL ✓
- EUROGYPSUM
- ESMA
- KPC ✓
- IDPA ✓

Industry

- NEPSI/Silica TF
- NEEIP ✓
- REACH Alliance
- ICMM
- CEFIC/ACC
- BusinessEurope
- IMA-NA ✓

Authorities

- DG EMPL
- DG ENTR
- NEPSI supporters
(HSE, BGs, Oviedo Instituto)
- OSHA-EU
- NIS
- MS (selection)
- ECHA/DG ENVI
- DG SANCO

9. Final step: Notification

1 December 2010: notification in the ECHA inventory

2 notifications by EUROSIL

- Quartz, respirable**
- Cristobalite, respirable**

Necessity of making separate notifications for concerned minerals is checked with REACH helpdesks

Quartz Sand Authorised as Pesticide

1 September 2009: Quartz Sand authorised as pesticide active substance
(Annex I Directive 91/414/EEC)

Draft Assessment Report (DAR) prepared by Rapporteur (Austria)
approved by 27 EU Member States on 28 October 2008

includes C&L for Quartz Sand under Pesticides legislation:

*Quartz Sand with < than 0.1% of particles with a diameter below 50 µm:
not classified*

*Quartz Sand with ≥ than 0.1% of particles with a diameter below 50 µm:
Carcinogen category 1, R49*

(Basis: IARC (1997), CICAD (2000), NIOSH (2002))

From a legal point of view this classification only valid for quartz sand
in the pesticide market.

This does not change the RCS C&L initiative approved by the IMA Board