

BPD - Review the evaluation of the first active substance

Graham Lloyd
Regulatory specialist
Stephoe & Johnson



STEPHOE & JOHNSON

Programme

- **Background**
- **Confidentiality**
- **Non submission of data/studies**
- **Data submission**
- **GLP requirements**
- **Submission of data**
- **Efficacy data**
- **Data protection**
- **Risk assessment**
- **Classification & labelling**

Evaluation reports - Index

- **Reports on both the Active Substance & Biocidal Product**

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Evaluation reports - Document III

Active substance

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Evaluation reports Document III

■ Biocidal product

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Evaluation reports

- There is a lot of duplication !
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Confidentiality

The report is published in full with confidential information blacked out

- Typical: 99.8% w/w minimum: [REDACTED] (please note that this is a confidential figure)
- steady-state concentration in global surface waters is very low ([REDACTED] (please note that this is a confidential figure) mg/l)
- Telephone [REDACTED] (please note that this is a confidential figure)

Background

- Approval as a biocide under 98/8/EC.
- Notified for use in Timber preservatives & insecticides
- The product is a gaseous fumigant
- The Rapporteur Member State is the KEMI in Sweden
- Also under evaluation as a Plant Protection Product where the Rapporteur Member State is PSD in the UK

Background

- For use by licensed professionals only
- A data rich substance
- Product is 40 years old
- RMS agreed that documents prepared for support under the Plant Protection Directive could be used for the BPD

Data submission

Odour: Not determined due to hazardous nature of the product

Explosive properties: Submitted theoretical + computer based evaluation

Eye & skin irritation: It is a gas. Toxic properties do not suggest a problem in over 40 years of use

Sensitisation: Technical difficulties & no evidence that the AS is an allergen

Effect of pH on the Log Pow: The molecule does not dissociate

Data submission

- The AS & BP are both data rich
- Long term studies include:
 - mechanistic study
 - Metabolism
 - Neurotoxicity
 - teratology in 2 species
 - fertility 1 year feeding studies
 - 2 x carcinogenicity studies (rat & mouse)
- Limited amount of ecotoxicology data supplied

GLP requirements

Some physical chemical data was not to GLP
Early study dates range from e.g. 1957

Conclusion of the RMS – All conducted tests and justifications for non submission of data are considered to be acceptable

Data submission

- **Residues in air**
 - Data submitted is acceptable
- **Residues in soil**
 - No method provided as product is not expected to partition into soil
- **Residues in water**
 - No method provided as product is not expect to be present in aquatic environment
- **Residue in body fluids**
 - Open literature methods for the ion - accepted

Efficacy data

A considerable amount of data is available

Most data was submitted on the product with a smaller dossier on the AS

- **Laboratory studies**
- **Field studies**
- **Reports from scientific journals**

Data protection

- Studies for which claims are made for the protection of data are marked in the evaluation documents
- Studies are marked where they have been used previously to support a national approval
- Data will be protected until 2010
OR
- 10 years from the date the AS is listed on Annex 1

Data protection

- No data protection for:
 - analytical determinations
 - reviews of data taken from scientific journals
 - some old studies/data
 - packaging specifications
 - justification statements for non submission of data

Classification & labelling current

T, Xi

R23/25

Toxic by inhalation and if swallowed

R36/37/38

Irritating to eyes, respiratory system and if swallowed

S1/2

Keep locked up and out of reach of children

S23

Do not breath the gas

S 37/39

Wear suitable gloves, eye face protection

S45

In case of accident or if you feel unwell, seek medical attention (show the label where possible)

Classification & labelling post evaluation

T, N

R23 Toxic by inhalation

R48/20 Harmful: danger of serious damage by prolonged exposure through inhalation

R50 Very toxic to aquatic organisms

S1/2 Keep locked up and out of reach of children

S45 In case of accident or if you feel unwell, seek medical attention (show the label where possible)

S61 Avoid release to the environment. Refer to special instructions/Safety data sheets

S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest

Agreed this is not necessary:

S60 This material and its container must be disposed of as hazardous waste*

Classification & labelling post evaluation

- Proposal in the 29th Adaptation to Technical Progress (ATP)
- Decision on the classification and labelling has been made by the European Chemicals Bureau (ECB)
- This overrides any company proposals

Exposure assessment

Operators

For use by trained licensed professional only

Operator exposure studies carried out with mill fumigators.

Considered to be intermittent & seasonal

*To calculate the **Acceptable Operator Exposure Concentration** took toxicity data and applied a 100 fold safety factor*

Exposure assessment

- ***Bystanders Incidental***
- People who pass by the mill when fumigation takes place
- This is considered a negligible risk

- ***Bystanders - residential***
- People who live near to a mill where the product is used
- General population, Infants, elderly & infirmed
- Apply same information used in the operator exposure assessment
- Exposure is below the AOEC

Exposure assessment - environmental

- **Air**
- Any emissions to partition to the atmosphere
 - Difficult to extrapolate movement to surface waters (oceans) and soils & uptake by plants – accepted
- **Water**
- No data submitted as will not enter the aquatic environment
- **Soil**
- No data submitted as will not be released to soil

Exposure assessment - environmental

- **Estimate of the Global Warming Potential**
- **Ozone depletion potential**
- **Tropospheric ozone formation potential**
- **Acidification potential**

Exposure assessment - environmental

- ***Re-entry workers***
- ***Only allowed into the treatment area once the level of the fumigant is below the **Acceptable Operator Exposure Concentration*****

**Thank you for
your attention**

**Graham Lloyd
Steptoe & Johnson
glloyd@steptoe.com**



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