

## Section A5 Effectiveness against target organisms and intended uses

### Subsection (Annex Point)

Official  
use  
only

- 5.1 Function (IIA5.1)** Insecticide, PT18
- 5.2 Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)**
- 5.2.1 Organism(s) to be controlled (IIA5.2)** Pyriproxyfen is a juvenile hormone mimic and insect growth regulator used to control a broad spectrum of insects. It is used in farm applications (animal houses) and waste treatment sites to control flies and to running and standing water to control mosquitoes
- Pyriproxyfen is used to control flies [REDACTED] and mosquitoes [REDACTED]
- 5.2.2 Products, organisms or objects to be protected (IIA5.2)** The products based on pyriproxyfen are designed to control fly and mosquito populations and provide both a nuisance and public health benefit
- 5.3 Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)**

**5.3.1 Effects on target organisms (IIA5.3)**

Pyriproxyfen is a juvenile hormone mimic and insect growth regulator. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

X

**5.3.2 Likely concentrations at which the A.S. will be used (IIA5.3)**

PT18

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

X

**5.4 Mode of action  
(including time delay)  
(IIA5.4)**

**5.4.1 Mode of action**

Pyriproxyfen is a juvenile hormone mimic and insect growth regulator used to control a broad spectrum of insects.

[Redacted]

**5.4.2 Time delay**

[Redacted]

**5.5 Field of use envisaged  
(IIA5.5)**

MG01:  
Disinfectants,  
general biocidal  
products

Not applicable

MG02:  
Preservatives

Not applicable

MG03: Pest control

Product types PT18, Insecticide

MG04: Other  
biocidal products

Not applicable

Further specification

Pyriproxyfen is a juvenile hormone mimic and insect growth regulator used to control a broad spectrum of insects. It is used in products to control flies and mosquitoes

**5.6 User  
(IIA5.6)**

**Industrial**

Not applicable

**Professional**

Pyriproxyfen is intended for use in professional products used in controlling flies in farm applications such as cattle pens, pig houses and poultry houses and also in waste treatment facilities. It is used to control mosquitoes in both running and standing water

**General public**

Not applicable

X

**5.7 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)**

**5.7.1 Development of resistance**

[REDACTED] There is no evidence of resistance development in biocide applications

**5.7.2 Management strategies**

As with all biocides an alternating regimen is recommended to minimise the potential for resistance development

**5.8 Likely tonnage to be placed on the market per year (IIA5.8)**

Considered to be commercially sensitive information. [REDACTED]

**Evaluation by Competent Authorities**

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

**Evaluation by Rapporteur Member State**

[REDACTED]

[REDACTED]



|            |            |
|------------|------------|
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]





| Function   | Field of use envisaged | Test substance | Test organism(s) | Test method | Test conditions | Test results: effects, mode of action, resistance | Reference*) |
|------------|------------------------|----------------|------------------|-------------|-----------------|---|-------------|
|            |                        | [REDACTED]     |                  |             | [REDACTED]      | [REDACTED]  |             |
| [REDACTED] | [REDACTED]             | [REDACTED]     | [REDACTED]       | [REDACTED]  | [REDACTED]      | [REDACTED]  | [REDACTED]  |

**References:**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**Table A5.3.1-02 Laboratory efficacy of Pyriproxyfen against mosquito larvae <sup>a,b</sup> (Taken from WHO WHOPES Report) Table 3.**

| <b>Species</b>             | <b>LC<sub>50</sub>/EI<sub>50</sub><sup>c</sup></b> | <b>LC<sub>95</sub>/EI<sub>95</sub><sup>c</sup></b> | <b>Reference</b> |
|----------------------------|--|--|------------------|
| <i>Ae aegypti</i>          | 0.33   | 2.6  | [REDACTED]       |
| <i>Ae aegypti</i>          | 0.023  | -  | [REDACTED]       |
| <i>Ae aegypti</i>          | 0.056  | -  | [REDACTED]       |
| <i>Ae aegypti</i>          | 0.0039   | -  | [REDACTED]       |
| <i>Ae albopictus</i>       | 0.11   | 0.38   | [REDACTED]       |
| <i>Ae taeniorhynchus</i>   | 0.01   | 0.052  | [REDACTED]       |
| <i>An albimanus</i>        | 0.016  | -  | [REDACTED]       |
| <i>An balabacensis</i>     | 0.04   | -  | [REDACTED]       |
| <i>An farauti</i>          | 0.0017   | -  | [REDACTED]       |
| <i>An gambiae</i>          | 0.025  | -  | [REDACTED]       |
| <i>An stephensi</i>        | 0.043  | -  | [REDACTED]       |
| <i>An quadrimaculatus</i>  | 1.3  | 17   | [REDACTED]       |
| <i>Cx pipiens pallens</i>  | 0.0046   | -  | [REDACTED]       |
| <i>Cx pipiens molestus</i> | 0.029  | -  | [REDACTED]       |
| <i>Cx quinquefasciatus</i> | 0.04   | 0.3 <sup>d</sup>                                   | [REDACTED]       |
| <i>Cx quinquefasciatus</i> | 0.018  | 0.16   | [REDACTED]       |
| <i>Cx quinquefasciatus</i> | 0.29   | 1.1 <sup>d</sup>                                   | [REDACTED]       |

| <b>Species</b>     | <b>LC<sub>50</sub>/EI<sub>50</sub><sup>c</sup></b> | <b>LC<sub>95</sub>/EI<sub>95</sub><sup>c</sup></b> | <b>Reference</b> |
|--------------------|--|--|------------------|
| <i>Cx tarsalis</i> | 0.085  | 0.32   | [REDACTED]       |
| <i>Cx tarsalis</i> | 0.021  | 0.25   | [REDACTED]       |

<sup>a</sup> mostly 4<sup>th</sup> instar larvae

<sup>b</sup> all toxicity values are in ppb

<sup>c</sup> lethal concentration to inhibit 50% or 95% adult emergence

<sup>d</sup> LC<sub>90</sub>/EI<sub>90</sub> values

**Table A5.3.1-03 Field efficacy of pyriproxyfen against mosquitoes in different habitats (Taken from WHO WHOPES Report)**  
**Table 4**

| <b>Species</b>                            | <b>Formulation<sup>a</sup></b> | <b>Dosage (a.i.)<sup>b</sup></b> | <b>%IE<sup>c</sup><br/>(range)</b> | <b>Control<br/>Duration</b> | <b>Reference</b> |
|---|--------------------------------|----------------------------------|------------------------------------|-----------------------------|------------------|
| <i>Ae aegypti</i>                         | GR                             | 25-50 ppb                        | 98-100                             | >3 wks                      | [REDACTED]       |
| <i>Ae melanimom</i>                       | GR                             | 0.0028-0.011 kg/ha               | 20-100                             | 4 days                      | [REDACTED]       |
| <i>Ae nigromaculis</i>                    | GR                             | 0.0028-0.11 kg/ha                | 69-100                             | 4 days                      | [REDACTED]       |
| <i>Ae nigromaculis &amp; Ae melanimom</i> | EC                             | 0.0028-0.0056 kg/ha              | 39-100                             | 3 days                      | [REDACTED]       |
| <i>An albimanus</i>                       | GR                             | 25-50 ppb                        | 95-100                             | >3 wks                      | [REDACTED]       |
| <i>An farauti</i>                         | EC                             | 0.1ppm                           | >70-100                            | >2 months                   | [REDACTED]       |
| <i>An punctuans</i>                       | GR                             | 0.02-0.1ppm                      | 100                                | 20 days -><br>2 months      | [REDACTED]       |
| <i>An minimus &amp; An maculatus</i>      | GR                             | 5 ppb                            | 70-100                             | 4 wks                       | [REDACTED]       |
| <i>Cx spp</i>                             | EC                             | 0.11 kg/ha                       | 100                                | >51 days                    | [REDACTED]       |
| <i>Cx pipiens pallens</i>                 | GR                             | 1-100 ppb                        | 91-100                             | 3-6 weeks                   | [REDACTED]       |
| <i>Cx quinquefasciatus</i>                | EC                             | 0.0056-0.045kg/ha                | 100                                | 2-14 days                   | [REDACTED]       |
| <i>Cx quinquefasciatus</i>                | EC                             | 0.11 kg/ha                       | 100                                | 2 months                    | [REDACTED]       |
| <i>Cx quinquefasciatus</i>                | GR                             | 25-50 ppb                        | 100                                | >3 wks                      | [REDACTED]       |

| <b>Species</b>   | <b>Formulation<sup>a</sup></b> | <b>Dosage (a.i.)<sup>b</sup></b>     | <b>%IE<sup>c</sup><br/>(range)</b> | <b>Control<br/>Duration</b> | <b>Reference</b> |
|--|--------------------------------|--------------------------------------|------------------------------------|-----------------------------|------------------|
| <i>Cx quinquefasciatus</i>                                       | EC& GR                         | 0.1 ppm                              | 100                                | 4-11 wks                    | [REDACTED]       |
| <i>Cx quinquefasciatus</i> & <i>Cx tarsalis</i> , <i>Cx peus</i> | EC                             | 0.1 kg/ha (single & multiple)        | 17-100                             | 7-68 days                   | [REDACTED]       |
| <i>Cx quinquefasciatus</i> & <i>Cx peus</i>                      | GR                             | 0.028-0.056 kg/ha                    | 26-66                              | 7 days                      | [REDACTED]       |
| <i>Cx tarsalis</i>   | MC &GR                         | 0.011-0.056 kg/ha 0.0056-0.028 kg/ha | 78-100<br>85-100                   | 7 days<br>7 days            | [REDACTED]       |
| <i>Cx tritaeniorhynchus</i>                                      | GR                             | 0.01 ppm                             | 43-100                             | > 3 wks                     | [REDACTED]       |
| <i>Psorophora columbiae</i>                                      | GR                             | 0.0056-0.011kg/ha                    | 100                                | 4 days                      | [REDACTED]       |

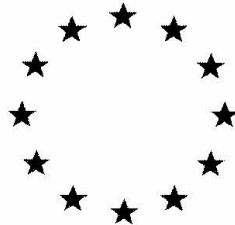
<sup>a</sup> GR=granula; EC= emulsifiable concentrate; MC= microencapsulated

<sup>b</sup> a.i. =active ingredient

<sup>c</sup> %IE= % inhibition of adult emergence



# **European Commission**



## **Pyriproxyfen**

**Document III-A  
Section 6 – Mammalian toxicology  
Study Summaries  
Active Substance**

**Rapporteur Member State: The Netherlands**

**January 2012**

Draft CA-report and Proposed Decision of The Netherlands in the context of the  
Possible inclusion of Pyriproxyfen in Annex I of Council Directive 98/8/EC

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Please refer to “Technical Notes for Guidance on Dossier Preparation including preparation and evaluation of study summaries under Directive 98/8 EC Concerning the Placing of Biocidal Products on the Market (Appendix 7.1 and 7.2)” for a list of the Standard Terms and Abbreviations used in this document.

## 6.1 Acute toxicity

### 6.1.1 Oral

#### Section A6.1.1/01 Acute toxicity - oral rat

##### Annex Point IIA6.1.1

### 1 REFERENCE

#### 1.1 Reference

[REDACTED]

#### 1.2 Data protection

Yes

##### 1.2.1 Data owner

Sumitomo Chemical Co., Ltd.

##### 1.2.2 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of entry into Annex I

### 2 GUIDELINES AND QUALITY ASSURANCE

#### 2.1 Guideline study

In-house method equivalent to US EPA FIFRA § 81-1, OECD 401, EEC B.1

#### 2.2 GLP

[REDACTED]

#### 2.3 Deviations

[REDACTED]

### 3 MATERIALS AND METHODS

#### 3.1 Test material

[REDACTED]

##### 3.1.1 Lot/Batch number

[REDACTED]

##### 3.1.2 Specification

[REDACTED]

##### 3.1.2.1 Description

[REDACTED]

##### 3.1.2.2 Purity

[REDACTED]

##### 3.1.2.3 Stability

[REDACTED]

#### 3.2 Test Animals

##### 3.2.1 Species

Rat

##### 3.2.2 Strain

[REDACTED]

##### 3.2.3 Source

[REDACTED]

##### 3.2.4 Sex

Male and female

##### 3.2.5 Age/weight at study initiation

[REDACTED]

Official  
use only

3.2.6 Number of animals per group [REDACTED]

3.2.7 Control animals Yes

**3.3 Administration/  
Exposure** Oral

3.3.1 Post exposure period 14 days

3.3.2 Type [REDACTED]

3.3.3 Concentration 0 [REDACTED] and 5000 mg/kg bw

3.3.4 Vehicle [REDACTED]

3.3.5 Concentration in vehicle [REDACTED]

3.3.6 Total volume applied [REDACTED]

3.3.7 Controls [REDACTED]

**3.4 Examinations** [REDACTED]

**3.5 Method of  
determination of LD<sub>50</sub>** [REDACTED]

**3.6 Further remarks** None

#### **4 RESULTS AND DISCUSSION**

**4.1 Clinical signs** [REDACTED]

**4.2 Pathology** [REDACTED]

**4.3 Other** [REDACTED]

**4.4 LD<sub>50</sub>** [REDACTED]

#### **5 APPLICANT'S SUMMARY AND CONCLUSION**

**5.1 Materials and methods** [REDACTED]



**Section A6.1.1/02 Acute toxicity - oral mouse**

**Annex Point IIA6.1.1**

**1 REFERENCE**

**1.1 Reference**

[REDACTED]

[REDACTED]

[REDACTED]

**1.2 Data protection**

Yes

1.2.1 Data owner

Sumitomo Chemical Co., Ltd.

1.2.2 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of entry into Annex I

**2 GUIDELINES AND QUALITY ASSURANCE**

**2.1 Guideline study**

In-house method equivalent to US EPA FIFRA § 81-1, OECD 401, EEC B.1

**2.2 GLP**

[REDACTED]

**2.3 Deviations**

[REDACTED]

**3 MATERIALS AND METHODS**

**3.1 Test material**

[REDACTED]

3.1.1 Lot/Batch number

[REDACTED]

3.1.2. Specification

[REDACTED]

3.1.2.1 Description

[REDACTED]

3.1.2.2 Purity

[REDACTED]

3.1.2.3 Stability

[REDACTED]

**3.2 Test Animals**

3.2.1 Species

Mice

3.2.2 Strain

[REDACTED]

3.2.3 Source

[REDACTED]

3.2.4 Sex

Male and female

Official  
use only

3.2.5 Age/weight at study initiation [REDACTED]

3.2.6 Number of animals per group [REDACTED]

3.2.7 Control animals Yes

**3.3 Administration/ Exposure** Oral

3.3.1 Post exposure period 14 days

3.3.2 Type [REDACTED]

3.3.3 Concentration 0, [REDACTED] 5000 mg/kg bw

3.3.4 Vehicle [REDACTED]

3.3.5 Concentration in vehicle [REDACTED]

3.3.6 Total volume applied [REDACTED]

3.3.7 Controls [REDACTED]

**3.4 Examinations** [REDACTED]

**3.5 Method of determination of LD<sub>50</sub>** [REDACTED]

**3.6 Further remarks** None

#### **4 RESULTS AND DISCUSSION**

**4.1 Clinical signs** [REDACTED]

**4.2 Pathology** [REDACTED]

**4.3 Other** [REDACTED]





|                          |            |
|--------------------------|------------|
| [REDACTED]               | [REDACTED] |
| <b>Comments from ...</b> |            |
| [REDACTED]               |            |
| [REDACTED]               |            |
| [REDACTED]               |            |
| [REDACTED]               |            |
| [REDACTED]               |            |
| [REDACTED]               |            |
| [REDACTED]               |            |

[REDACTED]

| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
|------------|------------|------------|------------|------------|
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |

**Section A6.1.1/03 Acute toxicity - oral dog**

**Annex Point IIA6.1.1**

**1 REFERENCE**

**1.1 Reference**

[REDACTED]

**1.2 Data protection**

Yes

1.2.1 Data owner

Sumitomo Chemical Co., Ltd.

1.2.2 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of entry into Annex I

**2 GUIDELINES AND QUALITY ASSURANCE**

**2.1 Guideline study**

In-house method equivalent to US EPA FIFRA § 81-1, OECD 401, EEC B.1

**2.2 GLP**

[REDACTED]

**2.3 Deviations**

[REDACTED]

**3 MATERIALS AND METHODS**

**3.1 Test material**

[REDACTED]

3.1.1 Lot/Batch number

[REDACTED]

3.1.2 Specification

[REDACTED]

3.1.2.1 Description

[REDACTED]

3.1.2.2 Purity

[REDACTED]

3.1.2.3 Stability

[REDACTED]

**3.2 Test Animals**

3.2.1 Species

Dog

3.2.2 Strain

[REDACTED]

3.2.3 Source

[REDACTED]

3.2.4 Sex

Male and female

3.2.5 Age/weight at study initiation

[REDACTED]

3.2.6 Number of animals per

[REDACTED]

Official  
use only

group

3.2.7 Control animals Yes

**3.3 Administration/  
Exposure** Oral

3.3.1 Post exposure period 14 days

3.3.2 Type [REDACTED]

3.3.3 Concentration 0, [REDACTED] 5000 mg/kg bw

3.3.4 Vehicle [REDACTED]

3.3.5 Concentration in  
vehicle [REDACTED]

3.3.6 Total volume applied [REDACTED]

3.3.7 Controls [REDACTED]

**3.4 Examinations** [REDACTED]

**3.5 Method of  
determination of LD<sub>50</sub>** [REDACTED]

**3.6 Further remarks** [REDACTED]

#### 4 RESULTS AND DISCUSSION

**4.1 Clinical signs** [REDACTED]

[REDACTED]

[REDACTED]

**4.2 Pathology** [REDACTED]

[REDACTED]



**4.3 Other**

**4.4 LD<sub>50</sub>**

**5 APPLICANT'S SUMMARY AND CONCLUSION**

**5.1 Materials and methods**

**5.2 Results and discussion**

**5.3 Conclusion**

The approximate lethal dose of pyriproxyfen was > 5000mg/kg bw. in dogs

**5.3.1 Reliability**

**5.3.2 Deficiencies**

| <b>Evaluation by Competent Authorities</b>   |            |
|--|------------|
| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |            |
| <b>Evaluation by Rapporteur Member State</b>   |            |
| [Redacted]   | [Redacted] |
| [Redacted]   | [Redacted] |
| [Redacted]   | [Redacted] |
| [Redacted]   | [Redacted] |
| [Redacted]   | [Redacted] |

|   |                                     |
|---|-------------------------------------|
| <p>[REDACTED]</p> <p>[REDACTED]</p>   | <p>[REDACTED]</p> <p>[REDACTED]</p> |
| <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> | <p>[REDACTED]</p>                   |

## 6.1.2 Dermal

### Section A6.1.2/01 Acute toxicity - dermal rat

#### Annex Point IIA 6.1.2

### 1 REFERENCE

#### 1.1 Reference

[REDACTED]

#### 1.2 Data protection

Yes

##### 1.2.1 Data owner

Sumitomo Chemical Co., Ltd.

##### 1.2.2 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of entry into Annex I

### 2 GUIDELINES AND QUALITY ASSURANCE

#### 2.1 Guideline study

In-house method equivalent to US EPA FIFRA§ 81-2, OECD 402, EEC B.3

#### 2.2 GLP

[REDACTED]

#### 2.3 Deviations

[REDACTED]

### 3 MATERIALS AND METHODS

#### 3.1 Test material

[REDACTED]

##### 3.1.1 Lot/Batch number

[REDACTED]

##### 3.1.2 Specification

[REDACTED]

##### 3.1.2.1 Description

[REDACTED]

##### 3.1.2.2 Purity

[REDACTED]

##### 3.1.2.3 Stability

[REDACTED]

#### 3.2 Test Animals

##### 3.2.1 Species

Rat

##### 3.2.2 Strain

[REDACTED]

##### 3.2.3 Source

[REDACTED]

##### 3.2.4 Sex

Male and female

##### 3.2.5 Age/weight at study initiation

[REDACTED]

##### 3.2.6 Number of animals per

[REDACTED]

Official  
use only

group

3.2.7 Control animals Yes

**3.3 Administration/  
Exposure** Dermal

3.3.1 Post exposure period 14 days

3.3.2 Area covered [REDACTED]

3.3.3 Occlusion [REDACTED]

3.3.4 Vehicle [REDACTED]

3.3.5 Concentration in  
vehicle [REDACTED]

3.3.6 Total volume applied [REDACTED]

3.3.7 Duration of exposure [REDACTED]

3.3.8 Removal of test  
substance [REDACTED]

3.3.9 Controls [REDACTED]

**3.4 Examinations** [REDACTED]

**3.5 Method of  
determination of LD<sub>50</sub>** [REDACTED]

**3.6 Further remarks** None

#### **4 RESULTS AND DISCUSSION**

**4.1 Clinical signs** [REDACTED]

**4.2 Pathology** [REDACTED]

**4.3 Bodyweight** [REDACTED]

**4.4 LD<sub>50</sub>** [REDACTED]







**Section A6.1.2/02 Acute toxicity – dermal mouse**

**Annex Point IIA 6.1.2**

**1 REFERENCE**

Official  
use only

**1.1 Reference**

[REDACTED]

[REDACTED]

[REDACTED]

**1.2 Data protection**

Yes

1.2.1 Data owner

Sumitomo Chemical Co., Ltd.

1.2.2 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of entry into Annex I

**2 GUIDELINES AND QUALITY ASSURANCE**

**2.1 Guideline study**

In-house method equivalent to US EPA FIFRA§ 81-2, OECD 402, EEC B.3

**2.2 GLP**

[REDACTED]

**2.3 Deviations**

[REDACTED]

**3 MATERIALS AND METHODS**

**3.1 Test material**

[REDACTED]

3.1.1 Lot/Batch number

[REDACTED]

3.1.2 Specification

[REDACTED]

3.1.2.1 Description

[REDACTED]

3.1.2.2 Purity

[REDACTED]

3.1.2.3 Stability

[REDACTED]

3.2 Test Animals

3.2.1 Species

Mice

3.2.2 Strain

[REDACTED]

3.2.3 Source

[REDACTED]

3.2.4 Sex

Male and female

3.2.5 Age/weight at study initiation [REDACTED]

3.2.6 Number of animals per group [REDACTED]

3.2.7 Control animals Yes

**3.3 Administration/ Exposure** Dermal

3.3.1 Postexposure period 14 days

3.3.2 Area covered [REDACTED]

3.3.3 Occlusion [REDACTED]

3.3.4 Vehicle [REDACTED]

3.3.5 Concentration in vehicle [REDACTED]

3.3.6 Total volume applied [REDACTED]

3.3.7 Duration of exposure [REDACTED]

3.3.8 Removal of test substance [REDACTED]

3.3.9 Controls [REDACTED]

**3.4 Examinations** [REDACTED]

**3.5 Method of determination of LD<sub>50</sub>** [REDACTED]

**3.6 Further remarks** None

#### **4 RESULTS AND DISCUSSION**

**4.1 Clinical signs** [REDACTED]

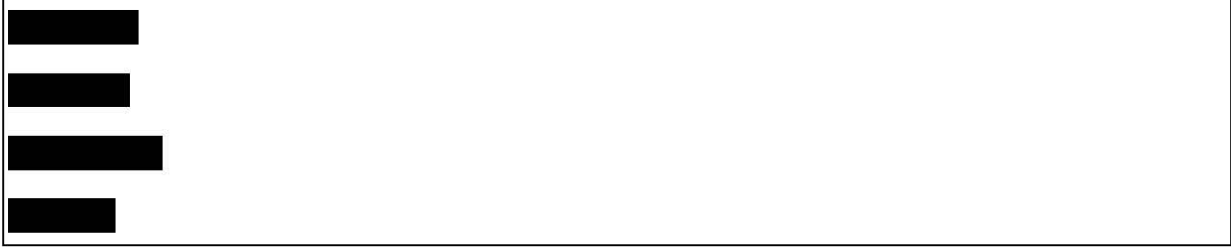
**4.2 Pathology** [REDACTED]

**4.3 Bodyweight** [REDACTED]

**4.4 LD<sub>50</sub>** [REDACTED]

#### **5 APPLICANT'S SUMMARY AND CONCLUSION**





### 6.1.3 Inhalation

#### Section A6.1.3/01 Acute toxicity - inhalation rat

##### Annex Point IIA 6.1.3

### 1 REFERENCE

#### 1.1 Reference

[REDACTED]

#### 1.2 Data protection

Yes

##### 1.2.1 Data owner

Sumitomo Chemical Co., Ltd.

##### 1.2.2 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of entry into Annex I

### 2 GUIDELINES AND QUALITY ASSURANCE

#### 2.1 Guideline study

In-house method equivalent to OECD 403, EEC B.2

#### 2.2 GLP

[REDACTED]

#### 2.3 Deviations

[REDACTED]

### 3 MATERIALS AND METHODS

#### 3.1 Test material

[REDACTED]

##### 3.1.1 Lot/Batch number

[REDACTED]

##### 3.1.2 Specification

[REDACTED]

##### 3.1.2.1 Description

[REDACTED]

##### 3.1.2.2 Purity

[REDACTED]

##### 3.1.2.3 Stability

[REDACTED]

#### 3.2 Test Animals

##### 3.2.1 Species

Rat

##### 3.2.2 Strain

[REDACTED]

##### 3.2.3 Source

[REDACTED]

##### 3.2.4 Sex

Male and female

##### 3.2.5 Age/weight at study initiation

[REDACTED]

##### 3.2.6 Number of animals per group

[REDACTED]

Official  
use only

3.2.7 Control animals Yes, vehicle and negative control

**3.3 Administration/  
Exposure** Inhalation

3.3.1 Post exposure period 14 days

3.3.2 Concentrations Nominal concentration Not included in the report  
Analytical concentration 600 and 1300 mg/m<sup>3</sup>

3.3.3 Particle size of mists generated

[REDACTED]

3.3.4 Type or preparation of particles

[REDACTED]

3.3.5 Type of exposure

[REDACTED]

3.3.6 Vehicle

[REDACTED]

3.3.7 Concentration in vehicle

[REDACTED]

3.3.8 Duration of exposure 4 hours

3.3.9 Controls

[REDACTED]

**3.4 Examinations**

[REDACTED]

**3.5 Method of determination of LD<sub>50</sub>**

[REDACTED]

**3.6 Further remarks**

None

#### **4 RESULTS AND DISCUSSION**

**4.1 Clinical signs**

[REDACTED]

**4.2 Pathology**

[REDACTED]

**4.3 Body weight**

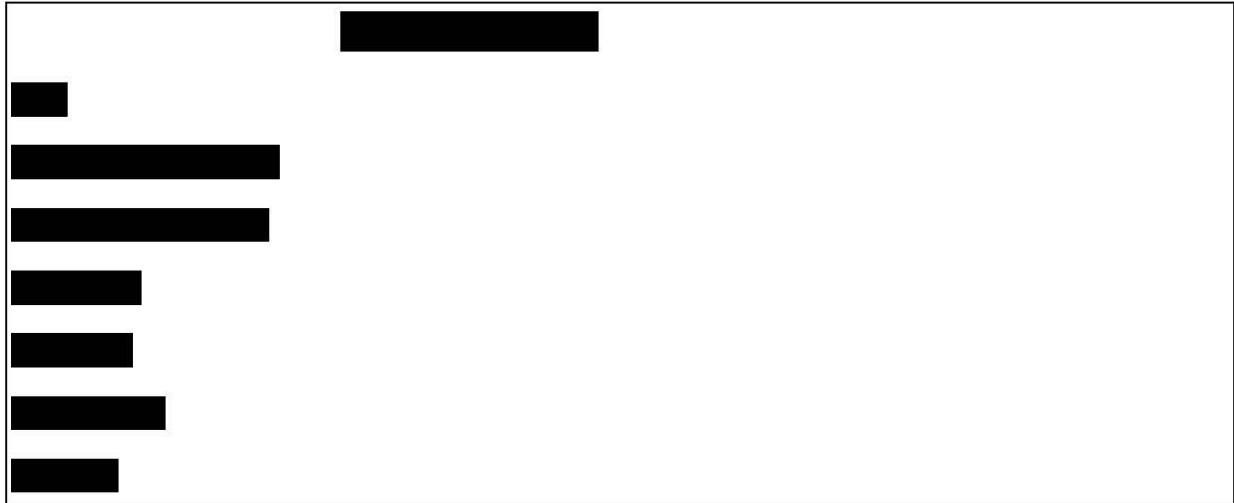
[REDACTED]

**4.4 LD<sub>50</sub>**

[REDACTED]







**Section A6.1.3/02 Acute toxicity – inhalation mouse**

**Annex Point IIA 6.1.3**

**1 REFERENCE**

**1.1 Reference**

[REDACTED]

**1.2 Data protection**

Yes

1.2.1 Data owner

Sumitomo Chemical Co., Ltd.

1.2.2 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of entry into Annex I

**2 GUIDELINES AND QUALITY ASSURANCE**

**2.1 Guideline study**

In-house method equivalent to OECD 403, EEC B.2

**2.2 GLP**

[REDACTED]

**2.3 Deviations**

[REDACTED]

**3 MATERIALS AND METHODS**

**3.1 Test material**

[REDACTED]

3.1.1 Lot/Batch number

[REDACTED]

3.1.2 Specification

[REDACTED]

3.1.2.1 Description

[REDACTED]

3.1.2.2 Purity

[REDACTED]

3.1.2.3 Stability

[REDACTED]

3.2 Test Animals

3.2.1 Species

Mouse

3.2.2 Strain

[REDACTED]

3.2.3 Source

[REDACTED]

3.2.4 Sex

Male and female

Official  
use only

3.2.5 Age/weight at study initiation [REDACTED]

3.2.6 Number of animals per group [REDACTED]

3.2.7 Control animals Yes, vehicle and negative control

**3.3 Administration/  
Exposure** Inhalation

3.3.1 Post exposure period 14 days

3.3.2 Concentrations Nominal concentration Not reported  
Analytical concentration 600 and 1300 mg/m<sup>3</sup>

3.3.3 Particle size of mists generated [REDACTED]

3.3.4 Type or preparation of particles [REDACTED]

3.3.5 Type of exposure [REDACTED]

3.3.6 Vehicle [REDACTED]

3.3.7 Concentration in vehicle [REDACTED]

3.3.8 Duration of exposure 4 h

3.3.9 Controls [REDACTED]

**3.4 Examinations** [REDACTED]

**3.5 Method of  
determination of LD<sub>50</sub>** [REDACTED]

**3.6 Further remarks** None

#### **4 RESULTS AND DISCUSSION**

**4.1 Clinical signs** [REDACTED]

**4.2 Pathology** [REDACTED]





## 6.1.4 Skin and eye irritation

### Section A6.1.4/01 Acute skin irritation - rabbit

#### Annex Point IIA.6.1.4

### 1 REFERENCE

#### 1.1 Reference

[REDACTED]

#### 1.2 Data protection

Yes

##### 1.2.1 Data owner

Sumitomo Chemical Co., Ltd

##### 1.2.2 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose for its entry into Annex I

### 2 GUIDELINES AND QUALITY ASSURANCE

#### 2.1 Guideline study

Yes

Ministry of Agriculture, Forestry and Fisheries (1985): Primary dermal irritation test, equivalent to US EPA FIFRA § 81-5, OECD 404, EEC B.4

#### 2.2 GLP

[REDACTED]

#### 2.3 Deviations

[REDACTED]

### 3 MATERIALS AND METHODS

#### 3.1 Test material

[REDACTED]

##### 3.1.1 Lot/Batch number

[REDACTED]

##### 3.1.2. Specification

[REDACTED]

##### 3.1.2.1 Description

[REDACTED]

##### 3.1.2.2 Purity

[REDACTED]

##### 3.1.2.3 Stability

[REDACTED]

#### 3.2 Test Animals

[REDACTED]

##### 3.2.1 Species

Rabbit

##### 3.2.2 Strain

[REDACTED]

##### 3.2.3 Source

[REDACTED]

##### 3.2.4 Sex

Male and female

Official  
use only

3.2.5 Age/weight at study initiation [REDACTED]

3.2.6 Number of animals per group [REDACTED]

3.2.7 Control animals No

**3.3 Administration/  
Exposure** Dermal

3.3.1 Application

3.3.1.1 Preparation of test substance [REDACTED]

3.3.1.2 Site and Preparation of Test Site [REDACTED]

3.3.2 Occlusion [REDACTED]

3.3.3 Vehicle [REDACTED]

3.3.4 Concentration in vehicle [REDACTED]

3.3.5 Total volume applied [REDACTED]

3.3.6 Removal of test substance [REDACTED]

3.3.7 Duration of exposure 4 hours

3.3.8 Post exposure period 72 hours

3.3.9 Controls None

**3.4 Examinations**

3.4.1 Clinical signs No

3.4.2 Dermal examination Yes

3.4.2.1 Scoring system [REDACTED]

3.4.2.2 Examination time points [REDACTED]

3.4.3 Other examinations None

**3.5 Further remarks**

**4 RESULTS AND DISCUSSION**

**4.1 Average score**







**Section 6.1.4/02 Acute eye irritation - rabbit**

**Annex Point IIA6.1.4**

**1 REFERENCE**

Official  
use only

**1.1 Reference**

[REDACTED]

**1.2 Data protection**

Yes

1.2.1 Data owner

Sumitomo Chemical Co., Ltd.

1.2.3 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of entry into Annex I

**2 GUIDELINES AND QUALITY ASSURANCE**

**2.1 Guideline study**

Yes

Ministry of Agriculture, Forestry and Fisheries (1985): Primary eye irritation test, equivalent to US EPA FIFRA § 81-4, OECD 405, EEC B.5

**2.2 GLP**

[REDACTED]

**2.3 Deviations**

[REDACTED]

**3 MATERIALS AND METHODS**

**3.1 Test material**

[REDACTED]

3.1.1 Lot/Batch No

[REDACTED]

3.1.2 Specification

[REDACTED]

3.1.2.1 Description

[REDACTED]

3.1.2.1 Purity

[REDACTED]

3.1.2.1 Stability

[REDACTED]

**3.2 Test animals**

3.2.1 Species

Rabbit

3.2.2 Strain

[REDACTED]

3.2.3 Source

[REDACTED]

3.2.4 Sex

Male and female

3.2.5 Age/ weight at study initiation [REDACTED]

3.2.6 Number of animals per group [REDACTED]

3.2.7 Control animals No

**3.3 Administration/  
Exposure**

3.3.1 Preparation of test substance [REDACTED]

3.3.2 Amount of active substance instilled [REDACTED]

3.3.3 Exposure period 72 hours

3.3.4 Post exposure period 72 hours

**3.4 Examinations**

3.4.1 Ophthalmoscopic examination [REDACTED]

3.4.1.1 Scoring system [REDACTED]

3.4.1.2 Examination time points 1h, 24h, 48h and 72hours

3.4.2 Other investigations None

**3.5 Further remarks**

**4 RESULTS AND DISCUSSION**

**4.1 Clinical signs** [REDACTED]

**4.2 Average score**

4.2.1 Cornea [REDACTED]

4.2.2 Iris [REDACTED]

4.2.3 Conjunctiva

4.2.3.1 Redness [REDACTED]

4.2.3.2 Chemosis [REDACTED]

**4.3 Reversibility** [REDACTED]





## 6.1.5 Skin sensitisation

### Section 6.1.5/01 Skin sensitisation

#### Annex Point IIA6.1.5

#### 1 REFERENCE

Official  
use only

##### 1.1 Reference

[REDACTED]

##### 1.2 Data protection

Yes

##### 1.2.1 Data owner

Sumitomo Chemical Co., Ltd.

##### 1.2.3 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of entry into Annex I

#### 2 GUIDELINES AND QUALITY ASSURANCE

##### 2.1 Guideline study

Yes

Maximization test: FIFRA 81-6, OECD 406, EEC B.6

##### 2.2 GLP

[REDACTED]

##### 2.3 Deviations

[REDACTED]

#### 3 MATERIALS AND METHODS

##### 3.1 Test material

[REDACTED]

##### 3.1.1 Lot/Batch No

[REDACTED]

##### 3.1.2 Specification

[REDACTED]

##### 3.1.2.1 Description

[REDACTED]

##### 3.1.2.2 Purity

[REDACTED]

##### 3.1.2.3 Stability

[REDACTED]

##### 3.1.2.4 Preparation of test substance for application

[REDACTED]

3.1.2.5 Pre test performed on irritant effects

Yes

**3.2 Test animals**

3.2.1 Species

Guinea pigs

3.2.2 Strain

[REDACTED]

3.2.3 Source

[REDACTED]

3.2.4 Sex

Male

3.2.5 Age/ weight at study initiation

[REDACTED]

3.2.6 Number of animals per group

[REDACTED]

3.2.7 Control animals

Yes

**3.3 Administration/  
Exposure**

3.3.1 Induction Schedule

day 0 – day 7, (Table A6.1.5-01)

3.3.2 Way of induction

Intradermal and topical

[REDACTED]

3.3.3 Concentrations used for induction

[REDACTED]

3.3.4 Concentration Freund's Complete Adjuvant (FCA)

[REDACTED]

3.3.5 Challenge schedule

Day 21; (Table A6.1.5-01)

3.3.6 Concentrations used for challenge

[REDACTED]

3.3.7 Rechallenge

No

3.3.8 Scoring schedule

[REDACTED]

3.3.9 Removal of the test substance

[REDACTED]

3.3.10 Positive control substance

Dinitrochlorobenzene

[REDACTED]



**3.4 Examinations**

[REDACTED]

**3.5 Further remarks**

None

**4 RESULTS**

**4.1 Results of pilot studies**

[REDACTED]

**4.2 Results of test**

**4.2.1 24 hr after challenge**

[REDACTED]

**4.2.2 48 hr after challenge**

[REDACTED]

**4.2.3 Other findings**

[REDACTED]

**4.3 Overall Result**

[REDACTED]

**5 APPLICANT'S SUMMARY AND CONCLUSION**

**5.1 Materials and methods**

[REDACTED]

**5.2 Results and discussion**

[REDACTED]

**5.3 Conclusion**















Pyriproxyfen was not a sensitiser in the Magnusson and Kligmann test

**5.3.1 Reliability**

[REDACTED]

**5.3.2 Deficiencies**

[REDACTED]

| <b>Evaluation by Competent Authorities</b>   |   |
|--|---|
| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |   |
| <b>Evaluation by Rapporteur Member State</b>   |   |
|               |    |
|               |    |
|               |    |
|               |   |
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|               |    |
|               |  |
| <b>Comments from...</b>  |   |
| <b>Date</b>  |   |
| <b>Materials and Methods</b>   |   |
| <b>Results and discussion</b>  |   |
| <b>Conclusion</b>  |   |
| <b>Reliability</b>   |   |
| <b>Acceptability</b>   |   |

**[REDACTED]**

| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
|------------|------------|------------|------------|
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |

**[REDACTED]**

| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
|------------|------------|------------|------------|
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |

## 6.2 Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

### 6.2.1 Absorption, distribution, metabolism and excretion in rats (phenoxyphenyl-<sup>14</sup>C)

Section 6.2.1/01  
Annex point IIA 6.2

Absorption, distribution, metabolism and excretion  
in rats (phenoxyphenyl-<sup>14</sup>C)

#### 1 REFERENCE

##### 1.1 Reference

[REDACTED]

##### 1.2 Data protection

Yes

##### 1.2.1 Data owner

Sumitomo Chemical Co., Ltd.

##### 1.2.2 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of entry into Annex I

#### 2 GUIDELINES AND QUALITY ASSURANCE

##### 2.1 Guideline study

In house method equivalent to US EPA FIFRA 85-1 General Metabolism, EU Directive 88/302/EEC, Part B Toxicokinetics

##### 2.2 GLP

[REDACTED]

##### 2.3 Deviations

[REDACTED]

#### 3 MATERIALS AND METHODS

##### 3.1 Test material

[REDACTED]

Official  
use only

3.1.1 Lot/Batch No

[REDACTED]

3.1.2 Specification

[REDACTED]

3.1.3 Description

[REDACTED]

3.1.4 Purity

[REDACTED]

3.1.5 Stability

[REDACTED]

3.1.6 Specific activity

[REDACTED]

**3.2 Test animals**

3.2.1 Species

Rat

3.2.2 Strain

[REDACTED]

3.2.3 Source

[REDACTED]

3.2.4 Sex

Male and female

3.2.5 Number of animals/group

[REDACTED]

[REDACTED]

**3.3 Administration**

Oral

3.3.1 Duration of treatment

Single and repeated doses

3.3.2 Dose levels

[REDACTED]

3.3.3 Sample collection

[REDACTED]

3.3.4 Analysis

[REDACTED]



## 4 RESULTS

### 4.1 Excretion

[REDACTED]

### 4.2 Tissue residues

[REDACTED]

### 4.3 Identity of metabolites

[REDACTED]

### 4.4 Biliary excretion

[REDACTED]

## 5 APPLICANT'S SUMMARY AND CONCLUSIONS

### 5.1 Materials and methods

[REDACTED]

[REDACTED]



**5.2 Results and discussion**

[Redacted]

[Redacted]

[Redacted]

[Redacted]

**5.3 Conclusion**

Pyriproxyfen was rapidly excreted in rats, mainly in the faeces. Tissue residues 7 days after dosing were generally low in all dose groups, except the fat. [Redacted]

[Redacted]

Absorption was calculated to be 63-69% of the dose

[Redacted]

**5.3.1 Reliability**

[Redacted]

**5.3.2 Deficiencies**

[Redacted]

| <b>Evaluation by Competent Authorities</b>   |  |
|--|--|
|  | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| <b>Evaluation by Rapporteur Member State</b> |  |
| [Redacted]                                   | [Redacted]   |
| [Redacted]                                   | [Redacted]   |
| [Redacted]                                   | [Redacted]   |

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]









## 6.2.2 Tissue distribution in rats (low dose)

### Section 6.2.2/01 Tissue distribution in rats (low dose)

#### Annex point IIA 6.2

#### 1 REFERENCE

Official  
use only

##### 1.1 Reference

[REDACTED]

##### 1.2 Data protection

Yes

##### 1.2.1 Data owner

Sumitomo Chemical Co., Ltd.

##### 1.2.3 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of entry into Annex I

#### 2 GUIDELINES AND QUALITY ASSURANCE

##### 2.1 Guideline study

In-house method equivalent to Directive 88/302/EEC, Part B Toxicokinetics,

##### 2.2 GLP

[REDACTED]

##### 2.3 Deviations

[REDACTED]

#### 3 MATERIALS AND METHODS

##### 3.1 Test material

[REDACTED]

##### 3.1.1 Lot/Batch No

[REDACTED]

[REDACTED]

##### 3.1.2 Specification

[REDACTED]

##### 3.1.3 Description

[REDACTED]

##### 3.1.4 Purity

[REDACTED]

[REDACTED]

##### 3.1.5 Stability

[REDACTED]

##### 3.1.6 Specific activity

[REDACTED]

##### 3.2 Test animals

##### 3.2.1 Species

Rats

3.2.2 Strain [REDACTED]

3.2.3 Source [REDACTED]

3.2.4 Sex Male and female

3.2.5 Number of animals/groups [REDACTED]

**3.3 Administration** Oral

3.3.1 Duration of treatment Single dose

3.3.2 Dose level 2 mg/kg

3.3.3 Sample collection [REDACTED]

3.3.4 Analysis [REDACTED]

#### 4 RESULTS

**4.1 Tissue residues** [REDACTED]

**4.2 Identity of metabolites** [REDACTED]

#### 5 APPLICANT'S SUMMARY AND CONCLUSIONS

**5.1 Materials and methods** [REDACTED]

**5.2 Results and discussion**

[Redacted]

[Redacted] The rate of elimination of radioactivity from tissues varied between 8 and 35 hours

The concentration of radioactivity was higher in the blood of males than in females. [Redacted]

[Redacted]

**5.3 Conclusion**

Highest concentrations of radioactivity were detected in blood, liver, kidney and fat of male rats and in the liver, kidney and fat of female rats. Radioactivity was rapidly eliminated from all tissues and residues were low 72 hours after dosing

5.3.1 Reliability

[Redacted]

5.3.2 Deficiencies

[Redacted]

| <b>Evaluation by Competent Authorities</b>   |            |
|--|------------|
| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |            |
| <b>Evaluation by Rapporteur Member State</b>   |            |
| [Redacted]   | [Redacted] |
| [Redacted]   | [Redacted] |
| [Redacted]   | [Redacted] |
| [Redacted]   | [Redacted] |

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|  | <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> |
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**Comments from...**

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| <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> |  |
|---|--|

The image shows a large table with a grid structure, mostly obscured by black redaction bars. The table has multiple columns and rows, with some cells containing text or numbers. The redaction covers the top, left, and bottom portions of the table, leaving a central grid area visible. The grid consists of approximately 10 columns and 20 rows. The top row is shaded grey. The left side of the table is completely redacted. The bottom row is also redacted. The central grid area contains some text, but it is mostly illegible due to the redaction. The text appears to be organized into several columns, possibly representing different categories or data points. The overall appearance is that of a data table from a regulatory document, where sensitive information has been redacted.







A large table with a grid structure, where most of the content is obscured by black redaction bars. The table has approximately 12 columns and 15 rows. The redaction is most prominent on the left side and in the middle of the grid.