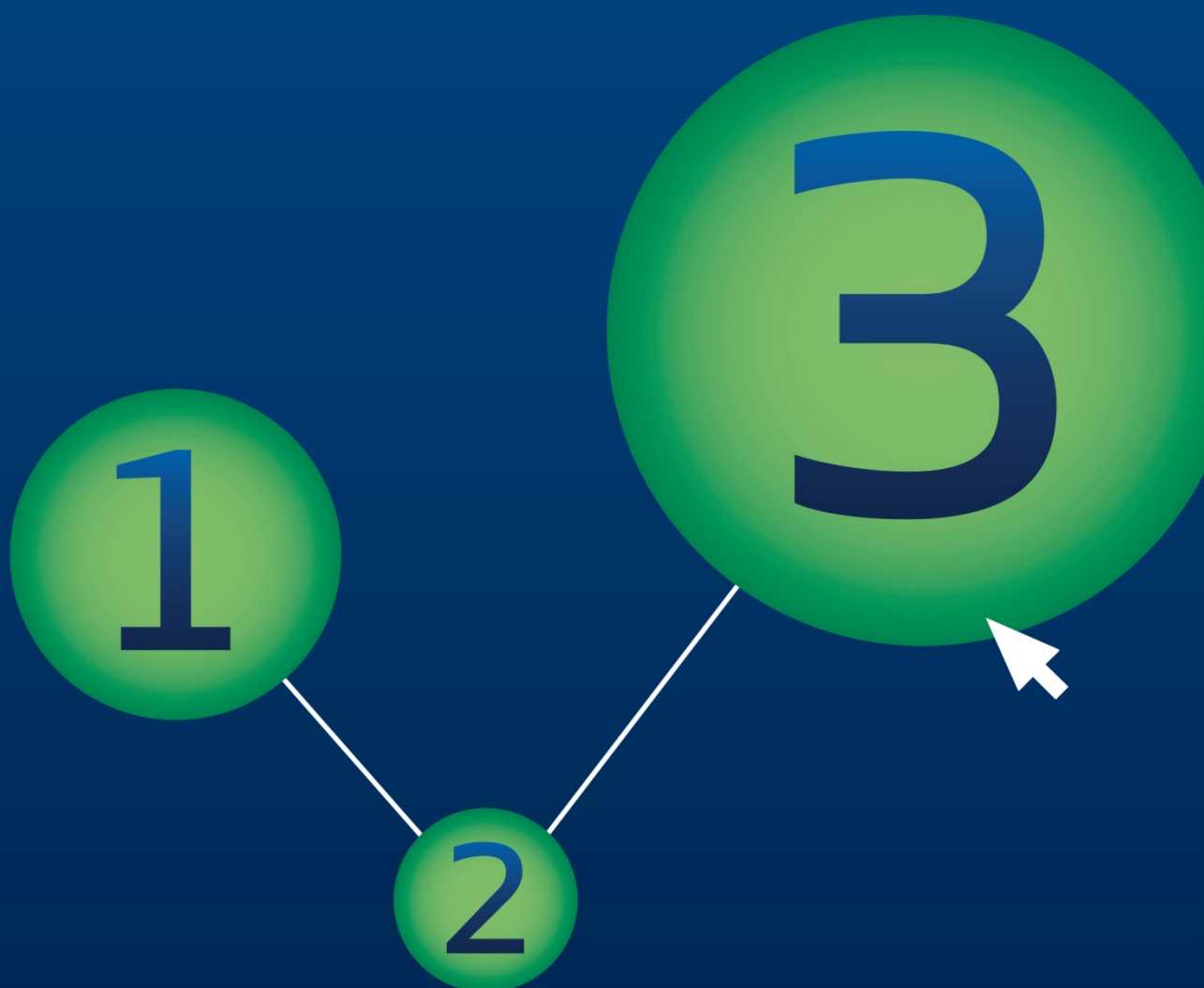


Biocides Submission Manual

Process of dissemination
Part 3: IUCLID section 8



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Version 2.0	IUCLID 6 screenshots, completely revised	July 2016

BSM Process of dissemination, Part 3: IUCLID section 8

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Introduction

Objective

This manual gives guidance on the online access provided by ECHA to information on active substances approved, and biocidal products authorised, under the Biocidal Products Regulation (BPR) (where the data is in IUCLID). It is aimed at industry, and in particular, at managers and technical experts in companies who are responsible for making sure that comprehensive information is entered in the dossiers.

Biocides Submission Manuals

This manual is part of the Biocides Submission Manual (BSM) series concerning technical guides, application instructions and process manuals and also includes:

Technical guides:

Using IUCLID, which describes how to prepare a general IUCLID dossier, giving you details on the different functionalities in IUCLID, as well as explaining the different sections contained within a dossier.

Using R4BP 3, which describes how to create user accounts in R4BP 3 through ECHA Accounts and gives a detailed description of the various functionalities of the system.

Using the SPC Editor, which describes how to prepare a summary of the product characteristics (SPC) required for certain application types.

Application instructions:

Application instruction manuals give guidance on how to submit applications concerning various processes concerning active substance approvals and biocidal product authorisations.

- **Active substances**
- **National authorisations**
- **Simplified authorisations**
- **Union authorisations**
- **Technical equivalence and chemical similarity**

Process manuals:

Invoicing in R4BP 3, which describes the general information related to invoices and credit notes issued by ECHA following the submission of an application.

Confidentiality requests for biocide applications, which describes how to make confidentiality claims in IUCLID and which dossier information can be claimed confidential.



All of the Biocides Submission Manuals, including the technical guides, application instructions and related processes can be found from the [ECHA website](#).

Article 67 of the Biocidal Products Regulation (BPR)

Article 67 of the Biocidal Products Regulation (BPR) stipulates that the European Chemicals Agency (ECHA) shall publish certain information it holds on approved biocidal active substances and authorised biocidal products free of charge over the internet. This information is published on the ECHA website, in the section 'Information on Chemicals'.

However, in certain cases information can be withheld, if the applicant submitting the information also indicates they wish to keep the information confidential, and submits a justification as to why publishing the information would be potentially harmful to the commercial interests of the applicant or any other party concerned. Relevant authority will then assess such justifications in accordance with Article 67(3) and (4), and where the justification is accepted, the information concerned will not be published. Claiming information confidential may be subject to a fee.

Where urgent action is essential to protect human health, safety or the environment, such as emergency situations, ECHA may disclose additional information, in accordance with Article 66(2). This will not happen in an automated way, and is therefore not covered in this manual.

This manual provides information about the online access to information on active substances approved, and biocidal products authorised, under the BPR.¹ The document will help readers to understand:

- what are the steps in the dissemination process; and
- which information will be made publicly available on the ECHA website.

The manual presents what ECHA directly publishes from the IUCLID dossiers and it does not cover information from other documents such as SPCs², assessment reports, etc.

Because of technical progress with IUCLID and the Dissemination portal, this manual will be regularly updated. We recommend that you check our website regularly to make sure that you have the most recent version of the document.

In addition to this manual, a specific dissemination preview will be made available for applicants in the near future. This tool will enable applicants to verify – when preparing a dossier in IUCLID – which information will be published on the ECHA website, as explained further below (see [Dissemination preview for IUCLID](#)).

The Dissemination portal

Web address

Information on chemicals can be accessed through the ECHA website; detailed information on approved active substances or authorised biocidal products can be accessed through the ECHA website following the below paths:

Active substances: ECHA Website > Information on Chemicals > Biocidal Active Substances:
<http://echa.europa.eu/information-on-chemicals/biocidal-active-substances>

¹ The dissemination obligations under Article 67 of the BPR also apply to information on active substances and biocidal products where the approval/authorisation application was submitted under the Biocidal Products Directive (BPD) (Directive 98/8/EC). The process for doing so is different to that described in this manual due to the use of IUCLID for the BPR dossiers.

² The information contained in the SPC associated with the authorisation of a biocidal product will be published on the ECHA website. It is the responsibility of the authorisation holder and Member State competent authority to make sure that this document does not contain confidential information.

Biocidal products: ECHA Website > Information on Chemicals > Biocidal Products:

<http://echa.europa.eu/information-on-chemicals/biocidal-products>

Searching in the portal

Before you can begin to search for active substances and/or biocidal products in the Dissemination portal, you have to acknowledge that you have taken note of the Legal Notice explaining the nature of the information, the right to use the information, and possible limits to the right to use the information.

You can search for an active substance in the portal by its name, EC number, CAS number, type, biocide ID and approval information.

A biocidal product can be searched by its name, asset number, product-type and name, EC number or CAS number, approval ID of its active substance as well as by authorisation data.

A list of all the active substances or biocidal products in the database can be obtained by searching without entering any search criteria.

Search results can be reordered by clicking on the individual column headers.

ECHA has also developed InfoCards and Brief Profiles for substances where details on the substance classification, uses and exposure and scientific properties are summarised and aggregated. Whilst currently they are primarily based on the data submitted in REACH registrations, they also include data from other sources, including the C&L Inventory, other REACH regulatory processes, and data from the BPR and PIC regulation.

Intellectual property rights

You should use the information available in the Dissemination portal with care. Reproduction and use or further distribution of the information is subject to copyright laws and may require the permission of the owner of that information.

Data protection periods apply to data submitted for the purposes of the BPD or of the BPR. Remember that in line with Article 59(1) of the BPR, the competent authorities may not use that data for the benefit of a subsequent applicant unless it has a letter of access or the data protection periods have expired.

The data protection periods are set in Article 60 of the BPR (*"Protection of Data held by competent authorities or the Agency"*) and Article 95(5) of the BPR (*"Transitional measures concerning access to the active substance dossier"*).

The Dissemination process

When is the information published?

For active substances, the process of disseminating information from an application dossier starts as soon as the European Commission has adopted an Implementing Regulation providing that the active substance is approved.

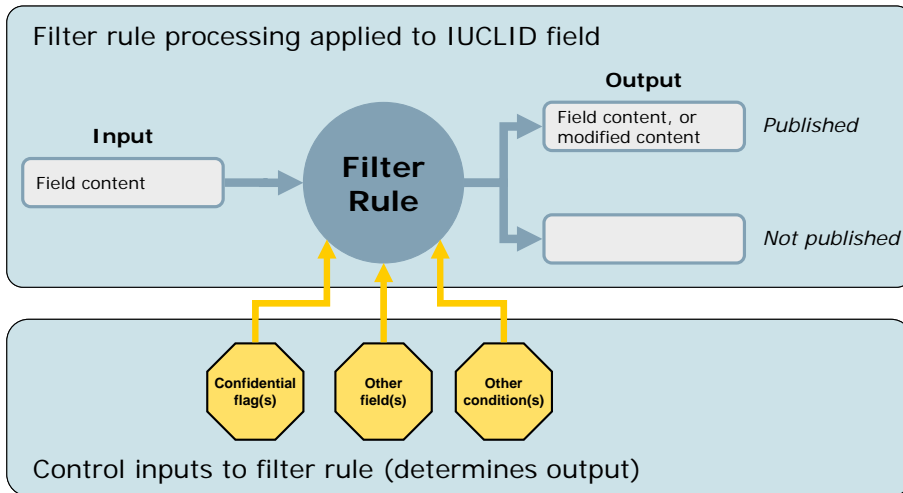
For biocidal products, the dissemination process starts from the date a biocidal product is authorised.

At this point, the associated dossier – which by now only contains confidentiality requests upheld by the relevant authority – is prepared for dissemination, as described below:

Filtering

The most important step in the dissemination process of the IUCLID information is the filtering step in which information not meant to be published is removed from the dossier, along with information flagged or claimed to be confidential (Figure 1).

Figure 1: Filter rules



The filtering of IUCLID dossiers is performed by an IT tool which has been programmed with Filter rules. Filter Rules are based on the Article 67 of the BPR and are applied to each field in the IUCLID dossier determining whether the field content should be published or not. After the filtering step is completed, the filtered dossier will contain only the information from the fields that is to be published.

Dossier filtering (the removal of information not to be published) is an automated process and is independent of which text you provide in a certain field. Please review your dossier before you submit it, to make sure the correct content is provided. If you provide confidential information in a field which is set to be published (e.g. the guidance on safe use), **the information will become visible on the internet.**

In this manual (consisting of four separate parts), you can see the filter rule that applies for all IUCLID 6 fields from the *BPR Active substance information* and *BPR Biocidal product authorisation* templates. The filter rules are explained in the [legend](#).

The other BPR templates for the substances (substances of concern and non-active substances) and representative biocidal products are currently not covered in this manual. Further information on how this information will be published will be made available in due time.

Publication

ECHA disseminates information at substance/product level. All documents and information from a IUCLID dossier will be linked to other relevant substance data identifiers. After the filtering step, the dossier is processed to create a set of html web pages. A batch of these web pages is regularly published on the ECHA website. As part of the same step, the relevant data and metadata are published to allow the search results to be searched and filtered.

Dissemination preview for IUCLID

ECHA is developing a IUCLID plugin to enable applicants to simulate which information from their IUCLID dossier will be removed during filtering, and which information will be made publicly available over the internet. The Dissemination preview will allow applicants to use it while they are preparing their BPR dossier in IUCLID. The purpose of the tool is to help

applicants to prepare dossiers that can be published without revealing confidential business information. More information on the tool will be available on the ECHA website in due time.

Confidentiality

The IUCLID template allows applicants to set confidentiality request flags on information covered by Article 67(3) and (4) of the BPR. For information that an applicant wishes to keep confidential, a confidentiality request must be justified and the request will only be implemented if it is upheld by the relevant authority. For guidance on confidentiality claims, please see the Biocides Submission Manual on the Process of confidentiality requests for biocide applications.³

³ http://echa.europa.eu/documents/10162/14938692/bsm_10_confidentiality_requests_en.pdf

Process of dissemination, Part 3: IUCLID section 8







In this manual, you can find the filter rule – illustrated with screenshots – for every field in section 8 of the IUCLID 6 dossier. The filter rule automatically determines if the content of the field is published on the ECHA website or not.

The legend on the next page briefly explains the different filter rules.

Unless otherwise stated, the rules of the section refer to the active substance template.

To allow for easy navigation, the sections in this manual use the same numbering as the sections in IUCLID in the appropriate BPR view. For information on the other sections of the IUCLID dossier, please consult the relevant part of the manual (the manual is divided into four parts, each dealing with separate groups of IUCLID sections).

Legend

	<p>Is always automatically published.</p> <ul style="list-style-type: none"> This rule concerns information listed in Article 67(1) and (2).
	<p>Is not automatically published.</p> <ul style="list-style-type: none"> This rule concerns information normally deemed to undermine the protection of the commercial interests of the persons concerned, or information which does not relate to the hazard and safe use of the substance.
	<p>Is automatically published unless confidentiality has been claimed on this section.</p> <ul style="list-style-type: none"> This rule concerns information listed in Article 67(3) and (4).
	<p>Fields that are always automatically published in the active substance dossier can be claimed confidential in the biocidal product dossier. Confidentiality flags and indication of endpoint addressed will be published.</p> <ul style="list-style-type: none"> This rule concerns information listed in Article 67(4).
	<p>The bibliographic references author, title, and source are published according to the following rule, with the most important criteria listed first:</p> <ul style="list-style-type: none"> are not published if the endpoint record is claimed confidential, unless the reference type is publication, review article or handbook; are not published if the reference type is study report or company data; are not published if at least one of following is provided: testing lab, report number, owner company or study number.
	<p>This information will be published from other source (e.g. SPC, R4BP) and not from the IUCLID dossier.</p>

Any confidentiality claim must be justified and the claim will only be implemented if it is upheld by the relevant authority. Justifications for claiming the confidentiality are not published.

Note to the legend

Field with a link

Fields containing a link to a record or information do not carry a filter rule as information they contain is published according to the individual filter rules set within the given record or information to which they refer.

Test material and identity of transformation products – conditioned filter rule

The test material and the identity of transformation products will be published unless:

- the reference substance describing the material itself is flagged confidential, or
- the endpoint study record is flagged confidential.

Justification for type of information – conditioned filter rule

Justification for type of information will be published unless:

- the reference substances linked to the endpoint study record have been flagged confidential, or
- the endpoint study record is flagged confidential.


For read-across, the information is not published if the study record in the related information is flagged confidential, or the test material reference substance in the related information is flagged confidential.

(Robust) study summary data



Fields referring to (robust) study summary data will only be published if the endpoint study record is not requested confidential.

8. Toxicological information

8.0 Toxicological profile for humans and animals (AEL) (also in Biocidal Product)


NB: Biocidal Product  → 

Administrative data ^

Human health hazard characteristics / Human health hazard characteristics ^



Tier

 ...


Systemic AEL (Acceptable Exposure Level) / Systemic AEL (Acceptable Exposure Level) ^

Long term exposure / Long term exposure ^


AEL chronic

  ...

Most sensitive endpoint



 ...

Route of original study


 ...

AEL related information / AEL related information ^



AEL derivation method



 ... Other  ...

Overall assessment factor (AF)


 ...

Dose descriptor starting point (after route to route extrapolation)


 ... Other  ...

  ...


Justification for route to route extrapolation

 ...


AF for dose response relationship

 ...


Justification

 ...


AF for differences in duration of exposure

 ...


Justification

 ...


AF for interspecies differences

 ...


Justification

 ...


AF for other intraspecies differences

 ...


Justification

 ...

AF for intraspecies differences

 ...

Justification

 ...

AF for the quality of the whole database
 ...

Justification
 ...

AF for remaining uncertainties
 ...

Justification
 ...

Justification and comments
 ...

Medium term exposure / Medium term exposure ^

AEL medium-term
 ... ▾

Most sensitive endpoint
 ... ▾

Route of original study
 ... ▾

AEL related information / AEL related information ^

AEL derivation method
 ... ▾ Other ...

Overall assessment factor (AF)
 ...

AEL extrapolated from long term AEL

Dose descriptor starting point (after route to route extrapolation)
 ... ▾ Other ...

... ▾

Justification for route to route extrapolation
 ...

AF for dose response relationship
 ...

Justification
 ...

AF for differences in duration of exposure
 ...

Justification
 ...

AF for interspecies differences
 ...

Justification
 ...

AF for other intraspecies differences
 ...

Justification
 ...

AF for intraspecies differences
 ...

Justification
 ...

AF for the quality of the whole database
 ...

Justification
 ...

AF for remaining uncertainties
 ...

Justification
 ...

Justification and comments
 ...

Acute/short term exposure ^

AEL acute
 ...

Most sensitive endpoint
 ...

Route of original study
 ...

AEL related information / AEL related information ^

AEL derivation method
 ... Other ...

Overall assessment factor (AF)
 ...

AEL extrapolated from long term AEL

Dose descriptor starting point (after route to route extrapolation)
 ... Other ...

...

Justification for route to route extrapolation
 ...

AF for dose response relationship
 ...

Justification
 ...

AF for differences in duration of exposure
 ...

Justification
 ...

AF for interspecies differences
 ...

Justification
 ...

AF for other intraspecies differences
 ...

Justification
 ...

AF for intraspecies differences
 ...

Justification
 ...

AF for the quality of the whole database

Justification

AF for remaining uncertainties

Justification

Justification and comments

External Reference Values for Route-Specific Effects ^

Route

AEC (Acceptable Exposure Concentration)

Most sensitive endpoint

Route of original study

AEC derivation method
 Other

Overall assessment factor (AF)

Dose descriptor starting point (after route to route extrapolation)
 Other

Justification for route to route extrapolation

AF for dose response relationship

Justification

AF for differences in duration of exposure

Justification

AF for interspecies differences

Justification

AF for other intraspecies differences

Justification	<input type="text" value="A"/>	...
AF for intraspecies differences	<input type="text" value="A"/>	...
Justification	<input type="text" value="A"/>	...
AF for the quality of the whole database	<input type="text" value="A"/>	...
Justification	<input type="text" value="A"/>	...
AF for remaining uncertainties	<input type="text" value="A"/>	...
Justification	<input type="text" value="A"/>	...
Justification and comments	<input type="text" value="N"/>	...

Reference Values for exposure via Food ^

Reference Value	<input type="text" value="A"/>	...			
	<input type="text" value="A"/>	<input type="text" value="A"/>	...		
Most sensitive endpoint	<input type="text" value="A"/>	...			
Route of original study	<input type="text" value="A"/>	...			
Reference value derivation method	<input type="text" value="A"/>	Other	<input type="text" value="A"/>	...	
Overall assessment factor (AF)	<input type="text" value="A"/>	...			
Dose descriptor starting point (after route to route extrapolation)	<input type="text" value="A"/>	...	Other	<input type="text" value="A"/>	...
	<input type="text" value="A"/>	<input type="text" value="A"/>	...		
Justification for route to route extrapolation	<input type="text" value="A"/>	...			
AF for dose response relationship	<input type="text" value="A"/>	...			
Justification	<input type="text" value="A"/>	...			
AF for differences in duration of exposure	<input type="text" value="A"/>	...			
Justification	<input type="text" value="A"/>	...			
AF for interspecies differences	<input type="text" value="A"/>	...			
Justification	<input type="text" value="A"/>	...			

AF for the quality of the whole database	<input type="text" value="A"/>	...
Justification	<input type="text" value="A"/>	...
AF for remaining uncertainties	<input type="text" value="A"/>	...
Justification	<input type="text" value="A"/>	...
Justification and comments	<input type="text" value="N"/>	...

MRL (maximum residue limit) ^

MLR for:

...

MRL Value

Justification and comments

Drinking Water Limit ^

Value

...

Justification and comments

Non threshold carcinogenic substances / Non threshold carcinogenic substances ^

DMEL (Derived Minimum Effect Level)

...

Most sensitive endpoint

...

Route of original study

...

DMEL related information ^

DMEL derivation method

... Other

Overall assessment factor (AF)

Dose descriptor starting point (after route to route extrapolation)

...

...

Justification for route to route extrapolation

AF for dose response relationship

Justification

AF for differences in duration of exposure

Justification

AF for interspecies differences

Justification

AF for other intraspecies differences	<input type="text" value="A"/>	...
Justification	<input type="text" value="A"/>	...
AF for intraspecies differences	<input type="text" value="A"/>	...
Justification	<input type="text" value="A"/>	...
AF for the quality of the whole database	<input type="text" value="A"/>	...
Justification	<input type="text" value="A"/>	...
AF for remaining uncertainties	<input type="text" value="A"/>	...
Justification	<input type="text" value="A"/>	...
AF for nature of carcinogenic process	<input type="text" value="A"/>	...
Justification	<input type="text" value="A"/>	...
AF for point of comparison	<input type="text" value="A"/>	...
Justification	<input type="text" value="A"/>	...
Justification and comments	<input type="text" value="N"/>	...

8.1 Irritation (also in Biocidal Product)

NB: Biocidal Product **A** → **C**

Administrative data ^

A

Description of key information ^

A

Key value for chemical safety assessment ^

Skin irritation / corrosion ^

Link to relevant study records ^

Study name / type

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Endpoint conclusion ^

Endpoint conclusion

A
...
▼

Eye irritation ^

Link to relevant study records ^

Study name / type

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Endpoint conclusion ^

Endpoint conclusion

A
...
▼

Respiratory irritation ^

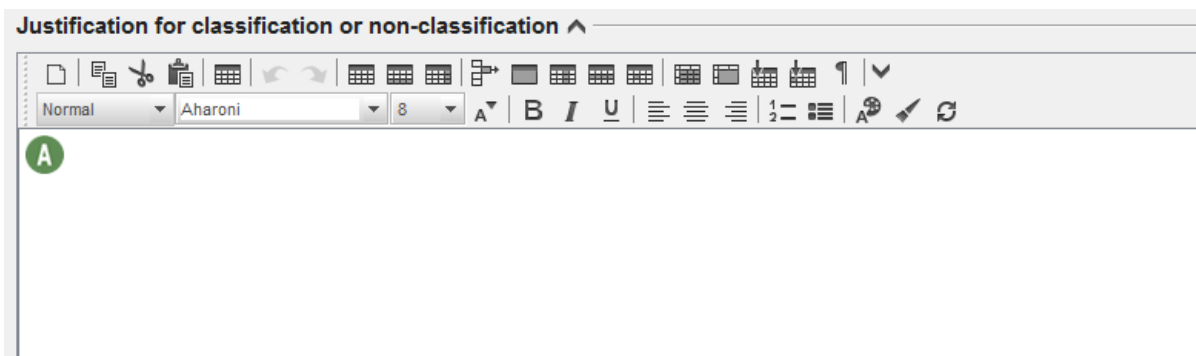
Endpoint conclusion ^

Endpoint conclusion

A
...
▼

Additional information ^

C



8.1.1 Skin irritation / corrosion (also in Biocidal Product)

NB: Biocidal Product **A** → **C**

Administrative data ^

A

Endpoint

A ... Remarks N ...

Type of information

A ... Other A ... Remarks N ...

Adequacy of study

A ...

Robust study summary N

Used for classification N

Used for SDS N

Study period

C ...

Reliability

A ... Other A ...

Rationale for reliability incl. deficiencies

C ... Other C ... Remarks N ...

Data waiving

C ...

Justification for data waiving

C

Justification for type of information

C

Attached justification

Attached justification	Reason / purpose
N	N

+ Add...
 ✎ Edit...
 ✕ Delete
 ↑ Move up
 ↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
 ✎ Edit...
 ✕ Delete
 ↑ Move up
 ↓ Move down
 ➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
 ✕ Delete
 ↑ Move up
 ↓ Move down
 ➤ Go to link target

Data access
 ... Other ... Remarks ...

Data protection claimed
 ... Remarks ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline
 ...

GLP compliance
 ... Remarks ...

Test material ^

Test material information
 > 🔗 ✕

Specific details on test material used for the study
 ...

In vitro test system ^

Test system
 ... Other ... Remarks ...

Source species
 ... Other ...

Cell type
 ... Other ...

Cell source
 ... Other ...

Source strain
 ... Other ...

Details on animal used as source of test system
 ...

Justification for test system used
 ...

Vehicle
 ... Other ... Remarks ...

Details on test system
 ...

Control samples	
▼ C	
Amount/concentration applied	
A ₂ ✕	▼
C	...
Duration of treatment / exposure	
C	...
Duration of post-treatment incubation (if applicable)	
C	...
Number of replicates	
C	...
Test animals ^	
Species	
A ... ▼ Other A	...
Strain	
A ... ▼ Other A ... Remarks N	...
Details on test animals and environmental conditions	
A ₂ ✕	▼
C	...
Test system ^	
Type of coverage	
A ... ▼ Other A	...
Preparation of test site	
C ... ▼ Other C ... Remarks N	...
Vehicle	
C ... ▼ Other C ... Remarks N	...
Controls	
▼ C	
Amount / concentration applied	
A ₂ ✕	▼
C	...
Duration of treatment / exposure	
C	...
Observation period	
C	...
Number of animals	
C	...
Details on study design	
A ₂ ✕	▼
C	...

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A B I U

N

Results and discussion ^

In vitro ^

Results

Irritation / corrosion...	Run / experiment	Value	Vehicle controls valid	Negative controls v...	Positive controls valid	Remarks on result
A	A	A	A	A	A	A

+ Add... Edit... Delete Move up Move down

Other effects / acceptance of results

A X

A

In vivo ^

Results

Irritation parameter	Basis	Time point	Score	Max. score	Reversibility	Remarks on result
A	A	A	A	A	A	A

+ Add... Edit... Delete Move up Move down

Irritant / corrosive response data

C

Other effects

A X

A

Any other information on results incl. tables ^

Normal Aharoni 8 A B I U

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U [list icons]

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... X Delete ↑ Move up ↓ Move down

Attached full study report

N

+ Add... Open Properties X Delete ↑ Move up ↓ Move down

Illustration (picture/graph)

N

Q Zoom + Load X Delete

Applicant's summary and conclusion ^

Interpretation of results

C	Other	C	Remarks	N
---	-------	---	---------	---

Conclusions

C

Executive summary

Normal Aharoni 8 A B I U [list icons]

C

8.1.2 Eye irritation (also in Biocidal Product)

NB: Biocidal Product A → C

Administrative data ^

A

Endpoint
A ... Remarks N ...

Type of information
A ... Other A ... Remarks N ...

Adequacy of study
A ...

Robust study summary N
 Used for classification N
 Used for SDS N

Study period
C ...

Reliability
A ... Other A ...

Rationale for reliability incl. deficiencies
C ... Other C ... Remarks N ...

Data waiving
C ...

Justification for data waiving
C

Justification for type of information
C

Attached justification	Reason / purpose
N	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data access
 ... Other ... Remarks ...

Data protection claimed
 ... Remarks ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline
 | X ...

GLP compliance
 ... Remarks ...

Test material ^

Test material information
 > ∞ X

Specific details on test material used for the study
 | X ...

Test animals / tissue source ^

Species
 ... Other ...

Strain
 ... Other ... Remarks ...

Details on test animals or tissues and environmental conditions
 | X ...

Test system ^

Vehicle
 ... Other ... Remarks ...

Controls

Amount / concentration applied
 | X ...

Duration of treatment / exposure
 ...

Observation period (in vivo)
 ...

Duration of post- treatment incubation (in vitro)

C ...

Number of animals or in vitro replicates

C ...

Details on study design

A₂ | X

C ...

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A⁺ B I U ...

N

Results and discussion ^

Results of ex vivo / in vitro study

Irritation parameter	Run / experiment	Value	Vehicle controls valid	Negative controls v...	Positive controls valid	Remarks on result
A	A	A	A	A	A	A

+ Add... Edit... Delete Move up Move down

Other effects / acceptance of results

A₂ | X

A ...

Results of in vivo study

Irritation parameter	Basis	Time point	Score	Max. score	Reversibility	Remarks on result
A	A	A	A	A	A	A

+ Add... Edit... Delete Move up Move down

Irritant / corrosive response data

C ...

Other effects

A₂ | X

A ...

Any other information on results incl. tables ^

Normal Aharoni 8 A⁺ B I U ...

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U [List Icons]

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... Delete Move up Move down

Attached full study report

N

+ Add... Open Properties Delete Move up Move down

Illustration (picture/graph)

N

Zoom Load Delete

Applicant's summary and conclusion ^

Interpretation of results

C Other C Remarks N

Conclusions

C

Executive summary

Normal Aharoni 8 A B I U [List Icons]

C

8.3 Sensitisation (also in Biocidal Product)

NB: Biocidal Product **A** → **C**

Administrative data ^

Description of key information ^

Normal Agency FB 8 A B I U

Key value for chemical safety assessment ^

Skin sensitisation ^

Link to relevant study records ^

Study name / type

+ Add... X Delete ↑ Move up ↓ Move down > Go to link target

Endpoint conclusion ^

Endpoint conclusion

A

Additional information

Normal Agency FB 8 A B I U

Respiratory sensitisation ^

Link to relevant study records ^

Study name / type

+ Add... X Delete ↑ Move up ↓ Move down > Go to link target

Endpoint conclusion ^

Endpoint conclusion

A

Additional information

Normal Agency FB 8 A B I U

8.3.1 Skin sensitisation (also in Biocidal Product)

NB: Biocidal Product **A** → **C**

Administrative data ^

A

Endpoint
A ... Remarks N ...

Type of information
A ... Other A ... Remarks N ...

Adequacy of study
A ...

Robust study summary N
 Used for classification N
 Used for SDS N

Study period
C ...

Reliability
A ... Other A ...

Rationale for reliability incl. deficiencies
C ... Other C ... Remarks N ...

Data waiving
C ...

Justification for data waiving
C

Justification for type of information
C

Attached justification	Reason / purpose
N	N

+ Add...
 ✎ Edit...
 ✕ Delete
 ↑ Move up
 ↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
 ✎ Edit...
 ✕ Delete
 ↑ Move up
 ↓ Move down
 ➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
 ✕ Delete
 ↑ Move up
 ↓ Move down
 ➤ Go to link target

Data access
 ... Other ... Remarks ...

Data protection claimed
 ... Remarks ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline
 ...

GLP compliance
 ... Remarks ...

Type of study
 ... Other ...

Justification for non-LLNA method
 ...

Test material ^

Test material information
 > 🔗 ✕

Specific details on test material used for the study
 ...

In vitro test system ^

Details on study design
 ...

In chemico test system ^

Details on study design
 ...

In vivo test system ^

Test animals ^

Species
 ... Other ...

Strain
 ... Other ... Remarks ...

Sex
 ...

Details on test animals and environmental conditions
 ...

Study design: in vivo (non-LLNA) ^

Induction

Route	Vehicle	Concentration / amount	Day(s)/duration	Adequacy of induction
A	C	C	C	C

+ Add... Edit... Delete Move up Move down

Challenge

No.	Route	Vehicle	Concentration / amount	Day(s)/duration	Adequacy of challenge
A	A	C	C	C	C

+ Add... Edit... Delete Move up Move down

No. of animals per dose

C ...

Details on study design

A₂ | X

C ...

Challenge controls

C ...

Positive control substance(s)

C ... Remarks N ...

Study design: in vivo (LLNA) ^

Vehicle

C ... Other C ... Remarks N ...

Concentration

C ...

No. of animals per dose

C ...

Details on study design

A₂ | X

C ...

Positive control substance(s)

C

Statistics

C ...

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A⁺ B I U | | | 1/2 = | A⁺ ↺

N

Results and discussion ^

Positive control results

C ...

In vitro / in chemico ^

Results

Key result	Parameter	Run / experiment	Value	Vehicle controls ...	Negative control...	Positive controls ...	Remarks on result
A <input type="checkbox"/>	A	A	A	A	A	A	A

+ Add... Edit... Delete Move up Move down

Other effects / acceptance of results

A | X ...

A ...

In vivo (non-LLNA) ^

Results

Key result	Reading	Hours after ch...	Group	Dose level	No. with + rea...	Total no. in gro...	Clinical observ...	Remarks on re...
A <input type="checkbox"/>	A	A	A	A	A	A	A	A

+ Add... Edit... Delete Move up Move down

In vivo (LLNA) ^

Results

Key result	Parameter	Value	Variability	Test group / Remarks	Remarks on result
A <input type="checkbox"/>	A	A	A	A	A

+ Add... Edit... Delete Move up Move down

Cellular proliferation data / Observations

A | X ...

A ...

Any other information on results incl. tables ^

Normal Aharoni 8 A B I U ...

A

Overall remarks, attachments ^

Overall remarks

N

Attached background material

Attached document	Remarks
N	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Attached full study report

N

+ Add...
📄 Open
✎ Properties
✕ Delete
↑ Move up
↓ Move down

Illustration (picture/graph)

N

🔍 Zoom
+ Load
✕ Delete

Applicant's summary and conclusion ^

Interpretation of results

C	Other	C	Remarks	N
---	-------	---	---------	---

Conclusions

C

Executive summary

C

8.3.2 Respiratory sensitisation (also in Biocidal Product)

NB: Biocidal Product **A** → **C**

Administrative data ^

Endpoint
A ... Remarks N ...

Type of information
A ... Other A ... Remarks N ...

Adequacy of study
A ...
 Robust study summary N
 Used for classification N
 Used for SDS N

Study period
C ...

Reliability
A ... Other A ...

Rationale for reliability incl. deficiencies
C ... Other C ... Remarks N ...

Data waiving
C ...

Justification for data waiving
C

Justification for type of information
C

Attached justification

Attached justification	Reason / purpose
N	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data access

N ... Other **N** ... Remarks **N** ...

Data protection claimed

N ... Remarks **N** ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline

A | X

GLP compliance

C ... Remarks **N** ...

Test material ^

Test material information

... > 🔗 X

Specific details on test material used for the study

A | X

C ...

Test animals ^

Species

A ... Other **A** ...

Strain

A ... Other **A** ... Remarks **N** ...

Sex

A ...

Details on test animals and environmental conditions

A | X

C ...

Test system ^

Route of induction exposure

A ... Other **A** ... Remarks **N** ...

Route of challenge exposure

A ... Other **A** ... Remarks **N** ...

Vehicle

C ... Other **C** ... Remarks **N** ...

Concentration

C ...

No. of animals per dose

C ...

Details on study design

A₁ X

C

Challenge controls

C

Positive control substance(s)

C

Negative control substance(s)

C

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A B I U

N

Results and discussion ^

Results

A

Positive control results ▲

C

Negative control results ▲

C

Any other information on results incl. tables ^

Normal Aharoni 8 A B I U

A

Overall remarks, attachments ^

Overall remarks

Normal | Aharoni | 8 | **A** | **B** | *I* | U | | | | |

N

Attached background material

Attached document	Remarks
N	N

+ Add... | Edit... | X Delete | ↑ Move up | ↓ Move down

Attached full study report

N

+ Add... | Open | Properties | X Delete | ↑ Move up | ↓ Move down

Illustration (picture/graph)

N

Q Zoom | + Load | X Delete

Applicant's summary and conclusion ^

Interpretation of results

C	... ▼ Other C	Remarks N	...
---	--	---	-----

Conclusions

C

Executive summary

Normal | Aharoni | 8 | **A** | **B** | *I* | U | | | | |

C

8.5 Genetic toxicity in vivo / in vitro

Administrative data ^

A

Key value for chemical safety assessment ^

Genetic toxicity in vitro ^

Description of key information ^

Normal Aharoni 8 A B I U

A

Link to relevant study records ^

Study name / type

+ Add... X Delete ↑ Move up ↓ Move down > Go to link target

Endpoint conclusion ^

Endpoint conclusion

A ...

Genetic toxicity in vivo ^

Description of key information ^

Normal Aharoni 8 A B I U

A

Link to relevant study records ^

Study name / type

+ Add... X Delete ↑ Move up ↓ Move down > Go to link target

Endpoint conclusion [^]
Endpoint conclusion
A

Mode of Action Analysis / Human Relevance Framework [^]

Normal Aharoni 8 A^v B I U

A

Additional information [^]

Normal Aharoni 8 A^v B I U

C

Justification for classification or non-classification [^]

Normal Aharoni 8 A^v B I U

A

8.5.1 Genetic toxicity in vivo

Administrative data ^

Endpoint
 ...

Type of information

Adequacy of study

Robust study summary
 Used for classification
 Used for SDS

Study period

Reliability
 ...

Rationale for reliability incl. deficiencies

Data waiving

Justification for data waiving

Justification for type of information

Attached justification

Attached justification	Reason / purpose

Cross-reference

Reason / purpose	Related information	Remarks

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks

Data access
 ... Other ... Remarks ...

Data protection claimed
 ... Remarks ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline
 | X

GLP compliance
 ... Remarks ...

Type of assay
 ... Other ...

Test material ^

Test material information

Specific details on test material used for the study
 | X

Method ^

Target gene

Species / strain

Species / strain	Details on mammalian c...	Additional strain chara...	Cytokinesis block (if us...	Metabolic activation	Metabolic activation sy...
<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="C"/>	<input type="text" value="A"/>	<input type="text" value="A"/>

+ Add... Edit... Delete Move up Move down

Test concentrations with justification for top dose

Vehicle
 | X

Controls

Negative controls	Solvent controls	True negative controls	Positive controls	Positive control substa...	Remarks
<input type="text" value="C"/>	<input type="text" value="C"/>	<input type="text" value="C"/>	<input type="text" value="C"/>	<input type="text" value="C"/>	<input type="text" value="C"/>

+ Add... Edit... Delete Move up Move down

Details on test system and conditions

A, | X

C

Rationale for test conditions

C

Evaluation criteria

C

Statistics

C

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A B I U

N

Results and discussion ^

Test results

Key result	Species / strain	Metabolic activ...	Genotoxicity	Cytotoxicity	Vehicle control...	Negative contr...	Positive control...	Remarks on re...
A	A	A	A	A	A	A	A	A

+ Add... Edit... X Delete ↑ Move up ↓ Move down

Additional information on results

A, | X

A

Any other information on results incl. tables ^

Normal Aharoni 8 A B I U

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U

N

Attached background material

Attached document	Remarks
N	N

Attached full study report

N

Illustration (picture/graph)

N

Applicant's summary and conclusion ^

Conclusions

C

Executive summary

Normal Aharoni 8 A B I U

C

8.5.4 Biocidal Product - Acute toxicity: product combinations

Administrative data ^

Endpoint
 ... Remarks

Type of information
 ... Other ... Remarks

Adequacy of study
 ...
 Robust study summary
 Used for classification
 Used for SDS

Study period

Reliability
 ... Other

Rationale for reliability incl. deficiencies
 ... Other ... Remarks

Data waiving

Justification for data waiving

Justification for type of information

Attached justification

Attached justification	Reason / purpose
<input type="text" value="N"/>	<input type="text" value="N"/>

+ Add... Edit... Delete Move up Move down

Cross-reference

Reason / purpose	Related information	Remarks
<input type="text" value="C"/>	<input type="text" value="C"/>	<input type="text" value="C"/>

+ Add... Edit... Delete Move up Move down Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
<input type="text" value="B"/>	<input type="text" value="B"/>	<input type="text" value="C"/>	<input type="text" value="C"/>	<input type="text" value="B"/>	<input type="text" value="N"/>	<input type="text" value="N"/>	<input type="text" value="C"/>	<input type="text" value="N"/>	<input type="text" value="C"/>	<input type="text" value="N"/>

+ Add... Delete Move up Move down Go to link target

Data access
 ... Other ... Remarks

Data protection claimed
 ... Remarks

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
C	C	C	C

Principles of method if other than guideline

A₂ | X

C

GLP compliance

C ... Remarks N

Limit test

C

Test material ^

Test material information

Specific details on test material used for the study

A₂ | X

C

Test animals ^

Species

C ... Other C

Strain

C ... Other C ... Remarks N

Sex

C

Details on test animals and environmental conditions

A₂ | X

C

Administration / exposure ^

Route of administration

C ... Other C

Vehicle

C ... Other C ... Remarks N

Details on exposure

C

Doses

C

No. of animals per sex per dose

C ...

Control animals

C ... **C** Other ... **N** Remarks ...

Details on study design

A | **X** **C** ...

Statistics

C ...

Any other information on materials and methods incl. tables ^

N

Results and discussion ^

Effect levels

Key result	Sex	Dose descriptor	Effect level	Based on	95% CL	Remarks on result
C <input type="checkbox"/>	C	C	C	C	C	C

+ Add... **E** Edit... **X** Delete **↑** Move up **↓** Move down

Mortality

C ...

Clinical signs

C ...

Body weight

C ...

Gross pathology

C ...

Other findings

A | **X** **C** ...

Other findings

A, X

C

 ...

Any other information on results incl. tables ^

C

Overall remarks, attachments ^

Overall remarks

N

Attached background material

Attached document	Remarks
N	N

+ Add...✎ Edit...✕ Delete↑ Move up↓ Move down

Attached full study report

N

+ Add...📄 Open✎ Properties✕ Delete↑ Move up↓ Move down

Illustration (picture/graph)

N

🔍 Zoom+ Load✕ Delete

Applicant's summary and conclusion ^

Conclusions

C

 ...

Executive summary

C

8.5.5 Genetic toxicity in vivo

Administrative data ^

📷
A

Endpoint

A
Remarks
N

Type of information

A
Other
Remarks
N

Adequacy of study

A

Robust study summary N

Used for classification N

Used for SDS N

Study period

C

Reliability

A
Other
A

Rationale for reliability incl. deficiencies

C
Other
C
Remarks
N

Data waiving

C

Justification for data waiving

C

Justification for type of information

C

Attached justification

Attached justification	Reason / purpose
N	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data access
 ... Other ... Remarks ...

Data protection claimed
 ... Remarks ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline
 | X

GLP compliance
 ... Remarks ...

Type of assay
 ... Other ...

Test material ^

Test material information

Specific details on test material used for the study
 | X

Test animals ^

Species
 ... Other ...

Strain
 ... Other ... Remarks ...

Details on species / strain selection
 ...

Sex
 ...

Details on test animals and environmental conditions
 | ...

Administration / exposure ^

Route of administration
 ... Other ...

Vehicle
 | ...

Details on exposure
 | ...

Duration of treatment / exposure
 ...

Frequency of treatment
 ...

Post exposure period
 ...

Doses / concentrations

Dose / conc.	Remarks
<input type="text" value="A"/>	<input type="text" value="A"/>

No. of animals per sex per dose
 ...

Control animals

Positive control(s)
 | ...

Examinations ^

Tissues and cell types examined
 ...

Details of tissue and slide preparation
 | ...

Evaluation criteria

C

Statistics

C

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A B I U

N

Results and discussion ^

Test results

Key result	Sex	Genotoxicity	Toxicity	Vehicle controls ...	Negative controls...	Positive controls ...	Remarks on result
A	<input type="checkbox"/>	A	A	A	A	A	A

+ Add... Edit... Delete Move up Move down

Additional information on results

A X

C

Any other information on results incl. tables ^

Normal Aharoni 8 A B I U

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... Delete Move up Move down

Attached full study report

N

+ Add... Open Properties Delete Move up Move down

Illustration (picture/graph)

N

Zoom Load Delete

Applicant's summary and conclusion ^

Conclusions

C ...

Executive summary

Normal Aharoni 8 A B I U List Bulleted Numbered Undo Redo

C

8.7 Acute toxicity (also in Biocidal Product under 8.5)

NB: Biocidal Product **A** → **C**

Administrative data ^

Description of key information ^

Normal Agency FB 8 **A** **B** **I** **U** [list icons] [undo] [redo]

Key value for chemical safety assessment ^

Acute toxicity: via oral route ^

Link to relevant study records ^

Study name / type

⊕ Add... ✕ Delete ↑ Move up ↓ Move down > Go to link target

Endpoint conclusion ^

Endpoint conclusion **A** ... ▾

Dose descriptor **A** ... ▾

A **A** ... ▾

Quality of whole database **A** ...

Acute toxicity: via inhalation route ^

Link to relevant study records ^

Study name / type

⊕ Add... ✕ Delete ↑ Move up ↓ Move down > Go to link target

Endpoint conclusion ^

Endpoint conclusion **A** ... ▾

Dose descriptor **A** ... ▾

A **A** ... ▾

Quality of whole database **A** ...

Acute toxicity: via dermal route ^

Link to relevant study records ^

Study name / type

Endpoint conclusion ^

Endpoint conclusion

A

Dose descriptor

A

A A

Quality of whole database

A ...

Additional information ^

Normal Agency FB 8 A B I U

C

Justification for classification or non-classification ^

Normal Agency FB 8 A B I U

A

8.7.1 Acute toxicity: oral (also in Biocidal Product under 8.5.1)NB: Biocidal Product **A** → **C**

Administrative data ^

Endpoint
 ... Remarks **N** ...

Type of information
 ... Other **A** ... Remarks **N** ...

Adequacy of study
 ...
 Robust study summary **N**
 Used for classification **N**
 Used for SDS **N**

Study period
 ...

Reliability
 ... Other **A** ...

Rationale for reliability incl. deficiencies
 ... Other **C** ... Remarks **N** ...

Data waiving
 ...

Justification for data waiving

Justification for type of information

Attached justification

Attached justification	Reason / purpose
N	N

+ Add... Edit... Delete Move up Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add... Edit... Delete Move up Move down Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add... Delete Move up Move down Go to link target

Data access
 ... Other ... Remarks ...

Data protection claimed
 ... Remarks ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline
 | X

GLP compliance
 ... Remarks ...

Test type
 ... Other ...

Limit test
 ...

Test material ^

Test material information
 > 🔗 X

Specific details on test material used for the study
 | X

Test animals ^

Species
 ... Other ...

Strain
 ... Other ... Remarks ...

Sex
 ...

Details on test animals and environmental conditions
 | X

Administration / exposure ^

Route of administration
 ... Other ...

Vehicle
 ... Other ... Remarks ...

Details on oral exposure
 | X

Doses

C
...

No. of animals per sex per dose

C
...

Control animals

C
...

Other

C
...

Remarks

N
...

Details on study design

C
...

Statistics

C
...

Any other information on materials and methods incl. tables

N

Results and discussion

Preliminary study

...

Effect levels

Key result	Sex	Dose descriptor	Effect level	Based on	95% CL	Remarks on result
A	A	A	A	A	A	A

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Mortality

C
...

Clinical signs

C
...

Body weight

C
...

Gross pathology

C
...

Other findings

C
...

Applicant's summary and conclusion ^

Interpretation of results

C ... Other **C** ... Remarks **N** ...

Conclusions

C ...

Executive summary

Normal Aharoni 8 A B I U | | | 1/2 | A ↻

C

8.7.2 Acute toxicity: inhalation (also in Biocidal Product under 8.5.2)

NB: Biocidal Product A → C

Administrative data ^

A

Endpoint A ... Remarks N ...

Type of information A ... Other A ... Remarks N ...

Adequacy of study A ...

Robust study summary N

Used for classification N

Used for SDS N

Study period C ...

Reliability A ... Other A ...

Rationale for reliability incl. deficiencies C ... Other C ... Remarks N ...

Data waiving C ...

Justification for data waiving C

Justification for type of information C

Attached justification

Attached justification	Reason / purpose
N	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data access
 ... Other ... Remarks ...

Data protection claimed
 ... Remarks ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline
 | X

GLP compliance
 ... Remarks ...

Test type
 ... Other ...

Limit test
 ...

Test material ^

Test material information
 > 🔗 X

Specific details on test material used for the study
 | X

Test animals ^

Species
 ... Other ...

Strain
 ... Other ... Remarks ...

Sex
 ...

Details on test animals and environmental conditions
 | X

Analytical verification of test atmosphere concentrations

C ... **Remarks** **N** ...

Duration of exposure

C **C** **C** **C** **C** ...

Remarks on duration

C ...

Concentrations

C ...

No. of animals per sex per dose

C ...

Control animals

C ... **Other** **C** ... **Remarks** **N** ...

Details on study design

C ...

Statistics

C ...

Any other information on materials and methods incl. tables ^

N

Results and discussion ^

Preliminary study

C ...

Effect levels

Key result	Sex	Dose descriptor	Effect level	Based on	95% CL	Exp. duration	Remarks on result
A <input type="checkbox"/>	A	A	A	A	A	A	A

⊕ Add... Edit... Delete Move up Move down

Mortality

C ...

Clinical signs

C ...

Body weight

C ...

Gross pathology

C ...

Other findings

C ...

Any other information on results incl. tables ^

Normal Aharoni 8 A B I U ...

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U ...

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... X Delete ↑ Move up ↓ Move down

Attached full study report

N

+ Add... Open Properties X Delete ↑ Move up ↓ Move down

Illustration (picture/graph)

N

Zoom Load X Delete

Applicant's summary and conclusion ^

Interpretation of results

C Other C Remarks N

Conclusions

C

Executive summary

Normal Aharoni 8 A B I U ...

C

8.7.3 Acute toxicity: dermal (also in Biocidal Product under 8.5.3)

NB: Biocidal Product A → C

Administrative data ^

A

Endpoint

A ... N

Type of information

A ... Other A ... N

Adequacy of study

A ...

Robust study summary N

Used for classification N

Used for SDS N

Study period

C ...

Reliability

A ... Other A ...

Rationale for reliability incl. deficiencies

C ... Other C ... N

Data waiving

C ...

Justification for data waiving

C

Justification for type of information

C

Attached justification

Attached justification	Reason / purpose
N	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data access

N ... Other **N** ... Remarks **N** ...

Data protection claimed

N ... Remarks **N** ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline

A | X

A ...

GLP compliance

C ... Remarks **N** ...

Test type

C ... Other **C** ...

Limit test

A ...

Test material ^

Test material information

... > 🔗 X

Specific details on test material used for the study

A | X

C ...

Test animals ^

Species

A ... Other **A** ...

Strain

A ... Other **A** ... Remarks **N** ...

Sex

A ...

Details on test animals and environmental conditions

A | X

C ...

Administration / exposure ^

Type of coverage
A ... Other A ...

Vehicle
C ... Other C ... Remarks N ...

Details on dermal exposure
A, | X ...

C ...

Duration of exposure
C ...

Doses
C ...

No. of animals per sex per dose
C ...

Control animals
C ... Other C ... Remarks N ...

Details on study design
A, | X ...

C ...

Statistics
C ...

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A B I U ...

N

Results and discussion ^

Preliminary study

C
...

Effect levels

Key result	Sex	Dose descriptor	Effect level	Based on	95% CL	Remarks on result
A <input type="checkbox"/>	A	A	A	A	A	A

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Mortality

C
...

Clinical signs

C
...

Body weight

C
...

Gross pathology

C
...

Other findings

C
...

Any other information on results incl. tables ^

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U ...

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... Delete Move up Move down

Attached full study report

N

+ Add... Open Properties Delete Move up Move down

Illustration (picture/graph)

N

Zoom Load Delete

Applicant's summary and conclusion ^

Interpretation of results

C Other C Remarks N

Conclusions

C


Executive summary

Normal Aharoni 8 A B I U ...

C

8.8 Toxicokinetics, metabolism studies in mammals

Administrative data ^





Link to relevant study record(s) ^

Study name / type

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target


Description of key information ^






Key value for chemical safety assessment ^


Bioaccumulation potential




Absorption rate - oral (%)




Absorption rate - dermal (%)




Absorption rate - inhalation (%)



Additional information ^





8.8.1 Further toxicokinetic and metabolism studies in mammals

Administrative data ^

Endpoint
 ... Remarks

Type of information
 ... Other ... Remarks

Adequacy of study

Robust study summary
 Used for classification
 Used for SDS

Study period

Reliability
 ... Other

Rationale for reliability incl. deficiencies
 ... Other ... Remarks

Data waiving

Justification for data waiving

Justification for type of information

Attached justification

Attached justification	Reason / purpose

Cross-reference

Reason / purpose	Related information	Remarks

+ Add... Edit... Delete Move up Move down Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks

+ Add... Delete Move up Move down Go to link target

Data access
 ... Other ... Remarks

Data protection claimed
 ... Remarks

Materials and methods ^

Objective of study

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>

Principles of method if other than guideline

GLP compliance

Test material ^

Test material information

Specific details on test material used for the study

Radiolabelling

Test animals ^

Species

Strain

Details on species / strain selection

Sex

Details on test animals and environmental conditions

Administration / exposure ^

Route of administration
A ... Other A ...

Vehicle
C ... Other C ... Remarks N ...

Details on exposure ⚠
A, X
C ...

Duration and frequency of treatment / exposure
C ...

Doses / concentrations

Dose / conc.	Remarks
C	C

+ Add... Edit... Delete Move up Move down

No. of animals per sex per dose
C ...

Control animals
C

Positive control
C ...

Details on study design
A, X
C ...

Details on dosing and sampling
A, X
C ...

Statistics
C ...

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A B I U | | | 1 2 | A

N

Results and discussion ^

Preliminary studies

C ...

Main ADME results

Type	Results
A	A

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Toxicokinetic / pharmacokinetic studies ^

Details on absorption

A ...

Details on distribution in tissues

A ...

Transfer into organs

Key result	Test no.	Transfer type	Observation
A <input type="checkbox"/>	A	A	A

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Details on excretion

A ...

Toxicokinetic parameters

Key result	Test no.	Toxicokinetic parameters
A <input type="checkbox"/>	A	A

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Metabolite characterisation studies ^

Metabolites identified

A ... ▼	Remarks A ...
--	--

Details on metabolites

A ...

Bioaccessibility ^

Bioaccessibility testing results

A

Any other information on results incl. tables ^

Normal Aharoni 8 A B I U

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... X Delete ↑ Move up ↓ Move down

Attached full study report

N

+ Add... Open Properties X Delete ↑ Move up ↓ Move down

Illustration (picture/graph)

N

Q Zoom + Load X Delete

Applicant's summary and conclusion ^

Conclusions

C

Executive summary

Normal Aharoni 8 A B I U

C

8.8.2 Dermal absorption (also in Biocidal Product under 8.6)

NB: Biocidal Product A → C

Administrative data ^

A

Endpoint A ... Remarks N ...

Type of information A ... Other A ... Remarks N ...

Adequacy of study A ...

Robust study summary N

Used for classification N

Used for SDS N

Study period C ...

Reliability A ... Other A ...

Rationale for reliability incl. deficiencies C ... Other C ... Remarks N ...

Data waiving C ...

Justification for data waiving C

Justification for type of information C

Attached justification	Reason / purpose
N	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data access

N ... Other **N** ... Remarks **N** ...

Data protection claimed

N ... Remarks **N** ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline

A | X

A ...

GLP compliance

C ... Remarks **N** ...

Test material ^

Test material information

... > 🔗 X

Specific details on test material used for the study

A | X

C ...

Radiolabelling

A ... Other **A** ... Remarks **N** ...

Test animals ^

Species

A ... Other **A** ...

Strain

A ... Other **A** ... Remarks **N** ...

Sex

A ...

Details on test animals and environmental conditions

A | X

C ...

Administration / exposure ^

Type of coverage

A ... Other **A** ... Remarks **N** ...

Vehicle

C ... Other **C** ... Remarks **N** ...

Duration of exposure

C ...

Doses
A₂ | X
C

No. of animals per group
C

Control animals
C ... Remarks N

Details on study design
A₂ | X
C

Details on in vitro test system (if applicable)
A₂ | X
C

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A⁺ B I U | | | 1/2 = | A

N

Results and discussion ^

Signs and symptoms of toxicity
C ... Remarks C

Dermal irritation
C ... Remarks C

Absorption in different matrices
A₂ | X
C

Total recovery
A₂ | X
C

Percutaneous absorption

Key result	Time point	Dose	Parameter	Absorption	Remarks on result
A	A	A	A	A	A

+ Add... Edit... Delete Move up Move down

Conversion factor human vs. animal skin

C

Any other information on results incl. tables ^

Normal Aharoni 8 A B I U | | | 1/2 = | A

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U | | | 1/2 = | A

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... Delete Move up Move down

Attached full study report

N

+ Add... Open Properties Delete Move up Move down

Illustration (picture/graph)

N

Zoom Load Delete

Applicant's summary and conclusion ^

Conclusions

C ...

Executive summary

Normal Aharoni 8 A B I U | | | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100

C

8.9 Repeated dose toxicity

8.9.4 Further repeated dose studies

Administrative data ^

A

Endpoint

A
Remarks N

Type of information

A
Other A
Remarks N

Adequacy of study

A

Robust study summary N

Used for classification N

Used for SDS N

Study period

C

Reliability

A
Other A

Rationale for reliability incl. deficiencies

C
Other C
Remarks N

Data waiving

C

Justification for data waiving

C

Justification for type of information

C

Attached justification

Attached justification	Reason / purpose
N	N

+ Add...
Edit...
X Delete
↑ Move up
↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
Edit...
X Delete
↑ Move up
↓ Move down
> Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
X Delete
↑ Move up
↓ Move down
> Go to link target

Data access

N ... Other N ... Remarks N ...

Data protection claimed

N ... Remarks N ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline

A₂ | X

A ...

GLP compliance

C ... Remarks N ...

Limit test

A ...

Test material ^

Test material information

... > 🔗 X

Specific details on test material used for the study

A₂ | X

C ...

Test animals ^

Species

A ... Other A ...

Strain

A ... Other A ... Remarks N ...

Details on species / strain selection

C ...

Sex

A ...

Details on test animals and environmental conditions

A₂ | X

C ...

Administration / exposure ^

Route of administration
A ... Other A ...

Vehicle
C ... Other C ... Remarks N ...

Details on exposure
C ...

Analytical verification of doses or concentrations
C ... Remarks N ...

Duration of treatment / exposure
C ...

Frequency of treatment
C ...

Doses / concentrations

Dose / conc.	Remarks
C	C

+ Add... Edit... Delete Move up Move down

No. of animals per sex per dose
C ...

Control animals
C

Details on study design
A, X
C ...

Examinations ^

Observations and examinations performed and frequency
A, X
C ...

Sacrifice and pathology
A, X
C ...

Other examinations
C ...

Statistics
C ...

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A B I U ...

N

Results and discussion ^

Results of examinations ^

Clinical signs
C ...

Description (incidence and severity)
C ...

Mortality
C ...

Description (incidence)
C ...

Body weight and weight changes
C ...

Description (incidence and severity)
C ...

Food consumption and compound intake (if feeding study)
C ...

Description (incidence and severity)
C ...

Food efficiency
C ...

Description (incidence and severity)
C ...

Water consumption and compound intake (if drinking water study)
C ...

Description (incidence and severity)
C ...

Ophthalmological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Haematological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Clinical biochemistry findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Urinalysis findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Behaviour (functional findings)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Immunological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Organ weight findings including organ / body weight ratios
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Gross pathological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...

Neuropathological findings

C
 ...

Description (incidence and severity)

C
 ...

Histopathological findings: non-neoplastic

C
 ...

Description (incidence and severity)

C
 ...

Histopathological findings: neoplastic

C
 ...

Description (incidence and severity)

C
 ...

Other effects

C
 ...

Description (incidence and severity)

C
 ...

Details on results

A
 ...

Effect levels ^

Key result	Dose descriptor	Effect level	Based on	Sex	Basis for effect level	Remarks on result
A	A	A	A	A	A	A

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Target system / organ toxicity ^

Key result	Critical effects o...	Lowest effectiv...	System	Organ	Treatment related	Dose response r...	Relevant for hu...
A	A	A	A	A	A	A	A


+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Any other information on results incl. tables ^

A

Overall remarks, attachments ^

Overall remarks



N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... Delete Move up Move down

Attached full study report

N

+ Add... Open Properties Delete Move up Move down

Illustration (picture/graph)

N


Zoom Load Delete

Applicant's summary and conclusion ^

Conclusions

C ...


Executive summary




C


8.9.5 Repeated dose toxicity: per route

Administrative data ^



Description of key information ^








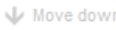

Key value for chemical safety assessment ^

Repeated dose toxicity: via oral route - systemic effects ^


Link to relevant study records ^

Study name / type


[Empty text area for study name / type]



    

Endpoint conclusion ^


Endpoint conclusion  ...

Dose descriptor



 ...

  ...


Study duration

 ...



Species

 ... Other  ...


Quality of whole database

 ...

System

 ... Other  ...

Organ



Repeated dose toxicity: inhalation - systemic effects ^

Link to relevant study records ^

Study name / type

+ Add... ✕ Delete ↑ Move up ↓ Move down ➤ Go to link target

Endpoint conclusion ^

Endpoint conclusion

A ▼

Dose descriptor

A ▼

A A ▼

Study duration

A ▼

Species

A ▼ Other A

Quality of whole database

A

System

A ▼ Other A

Organ

▼ A

Repeated dose toxicity: inhalation - local effects ^

Link to relevant study records ^

Study name / type

+ Add... ✕ Delete ↑ Move up ↓ Move down ➤ Go to link target

Endpoint conclusion ^

Endpoint conclusion

A ▼

Dose descriptor

A ▼

A A ▼

Study duration

A ▼

Species

A ▼ Other A

Quality of whole database

A

Repeated dose toxicity: dermal - systemic effects ^

[Link to relevant study records ^](#)

Study name / type

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Endpoint conclusion ^

Endpoint conclusion

A

... ▼

Dose descriptor

A

... ▼

A

A

... ▼

Study duration

A

... ▼

Species

A

... ▼
Other A ...

Quality of whole database

A

... ▼

System

A

... ▼
Other A ...

Organ

A

Repeated dose toxicity: dermal - local effects ^

[Link to relevant study records ^](#)

Study name / type

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Endpoint conclusion ^

Endpoint conclusion

A

... ▼

Dose descriptor

A

... ▼

A

A

... ▼

Study duration

A

... ▼

Species

A

... ▼
Other A ...

Quality of whole database

A

... ▼

8.9.5.1 Repeated dose toxicity: oral

Administrative data ^

Endpoint
A ... Remarks N ...

Type of information
A ... Other A ... Remarks N ...

Adequacy of study
A ...

Robust study summary N
 Used for classification N
 Used for SDS N

Study period
C ...

Reliability
A ... Other A ...

Rationale for reliability incl. deficiencies
C ... Other C ... Remarks N ...

Data waiving
C ...

Justification for data waiving
C

Justification for type of information
C

Attached justification

Attached justification	Reason / purpose
N	N

+ Add...
 ✎ Edit...
 ✕ Delete
 ↑ Move up
 ↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
 ✎ Edit...
 ✕ Delete
 ↑ Move up
 ↓ Move down
 ➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
 ✕ Delete
 ↑ Move up
 ↓ Move down
 ➤ Go to link target

Data access

N ... Other **N** ... Remarks **N** ...

Data protection claimed

N ... Remarks **N** ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline

A | X

GLP compliance

C ... Remarks **N** ...

Limit test

A ...

Test material ^

Test material information

... > 🔗 X

Specific details on test material used for the study

A | X

C ...

Test animals ^

Species

A ... Other **A** ...

Strain

A ... Other **A** ... Remarks **N** ...

Details on species / strain selection

C ...

Sex

A ...

Details on test animals and environmental conditions
A | X ⌵

C ...

Administration / exposure ^

Route of administration
A ... Other A ...

Details on route of administration
C ...

Vehicle
C ... Other C ... Remarks N ...

Details on oral exposure
A | X ⌵

C ...

Analytical verification of doses or concentrations
C ... Remarks N ...

Details on analytical verification of doses or concentrations
C ...

Duration of treatment / exposure
C ...

Frequency of treatment
C ...

Doses / concentrations

Dose / conc.	Remarks
C	C

+ Add... ✎ Edit... ✕ Delete ↑ Move up ↓ Move down

No. of animals per sex per dose
C ...

Control animals
⌵ C

Details on study design
A | X ⌵

C ...

Positive control
C ...

Examinations ^

Observations and examinations performed and frequency
A, X
C

Sacrifice and pathology
A, X
C

Other examinations
C

Statistics
C

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A B I U | | | 1 2 = | A

N

Results and discussion ^

Results of examinations ^

Clinical signs
C

Description (incidence and severity)
C

Mortality
C

Description (incidence)
C

Body weight and weight changes
C

Description (incidence and severity)
C

Food consumption and compound intake (if feeding study)
C

Description (incidence and severity)
C

Food efficiency
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Water consumption and compound intake (if drinking water study)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Ophthalmological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Haematological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Clinical biochemistry findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Urinalysis findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Behaviour (functional findings)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Immunological findings
<input type="text" value="C"/> ... ▼

Description (incidence and severity)	
<input type="text" value="C"/>	...
Organ weight findings including organ / body weight ratios	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Gross pathological findings	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Neuropathological findings	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Histopathological findings: non-neoplastic	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Histopathological findings: neoplastic	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Other effects	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Details on results	
<input type="text" value="C"/>	...

Effect levels ^

Key result	Dose descriptor	Effect level	Based on	Sex	Basis for effect level	Remarks on result
A	A	A	A	A	A	A

Target system / organ toxicity ^

Key result	Critical effects o...	Lowest effectiv...	System	Organ	Treatment related	Dose response r...	Relevant for hu...
A	A	A	A	A	A	A	A

Any other information on results incl. tables ^

Normal Aharoni 8 A^v B I U

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A^v B I U

N

Attached background material

Attached document	Remarks
N	N

Attached full study report

N

Illustration (picture/graph)

N

8.9.5.2 Repeated dose toxicity: inhalation

Administrative data ^

A

Endpoint
A ... Remarks N ...

Type of information
A ... Other A ... Remarks N ...

Adequacy of study
A ...

Robust study summary N
 Used for classification N
 Used for SDS N

Study period
C ...

Reliability
A ... Other A ...

Rationale for reliability incl. deficiencies
C ... Other C ... Remarks N ...

Data waiving
C ...

Justification for data waiving
C

Justification for type of information
C

Attached justification	Reason / purpose
N	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data access

N ... Other **N** ... Remarks **N** ...

Data protection claimed

N ... Remarks **N** ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline

A | X

A ...

GLP compliance

C ... Remarks **N** ...

Limit test

A ...

Test material ^

Test material information

Specific details on test material used for the study

A | X

C ...

Test animals ^

Species

A ... Other **A** ...

Strain

A ... Other **A** ... Remarks **N** ...

Details on species / strain selection

C ...

Sex

A ...

Details on test animals and environmental conditions

A | X

C ...

Administration / exposure ^

Route of administration
 ... Other

Type of inhalation exposure
 ... Other Remarks

Vehicle
 ... Other Remarks

Mass median aerodynamic diameter (MMAD)
 ... Other

Geometric standard deviation (GSD)

Remarks on MMAD

Details on inhalation exposure
 |

Analytical verification of doses or concentrations
 ... Remarks

Details on analytical verification of doses or concentrations

Duration of treatment / exposure

Frequency of treatment

Doses / concentrations

Dose / conc.	Remarks
<input type="text" value="C"/>	<input type="text" value="C"/>

+ Add... Edit... Delete Move up Move down

No. of animals per sex per dose

Control animals

Details on study design
 |

Positive control

Examinations ^

Observations and examinations performed and frequency

A₂ | X

C

Sacrifice and pathology

A₂ | X

C

Other examinations

C

Statistics

C

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A B I U

N

Results and discussion ^

Results of examinations ^

Clinical signs

C

Description (incidence and severity)

C

Mortality

C

Description (incidence)

C

Body weight and weight changes

C

Description (incidence and severity)

C

Food consumption and compound intake (if feeding study)

C

Description (incidence and severity)

C

Food efficiency
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Water consumption and compound intake (if drinking water study)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Ophthalmological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Haematological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Clinical biochemistry findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Urinalysis findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Behaviour (functional findings)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Immunological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...

Organ weight findings including organ / body weight ratios
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Gross pathological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Neuropathological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Histopathological findings: non-neoplastic
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Histopathological findings: neoplastic
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Other effects
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Details on results
<input type="text" value="A"/> ...

Effect levels

Key result	Dose descriptor	Effect level	Based on	Sex	Basis for effect level	Remarks on result
	<input type="checkbox"/>					

+ Add...
 Edit...
 Delete
 Move up
 Move down

Target system / organ toxicity

Key result	Critical effects o...	Lowest effectiv...	System	Organ	Treatment related	Dose response r...	Relevant for hu...
	<input type="checkbox"/>						

+ Add...
 Edit...
 Delete
 Move up
 Move down

Any other information on results incl. tables

Overall remarks, attachments

Overall remarks

Attached background material

Attached document	Remarks

+ Add...
 Edit...
 Delete
 Move up
 Move down

Attached full study report

+ Add...
 Open
 Properties
 Delete
 Move up
 Move down

Illustration (picture/graph)

Zoom
 Load
 Delete

Applicant's summary and conclusion ^

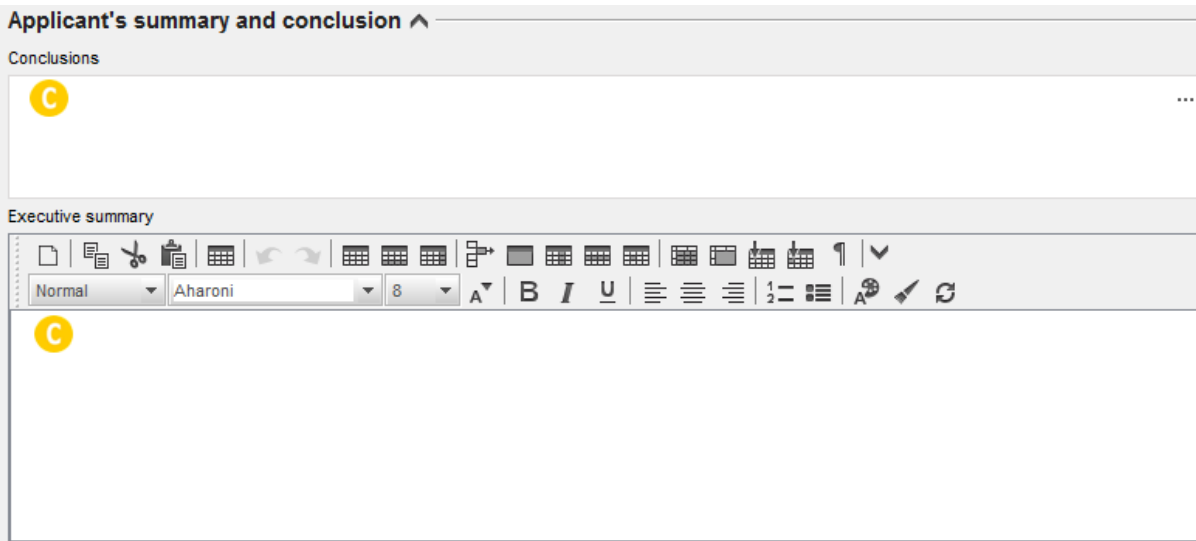
Conclusions

C ...

Executive summary

Normal Aharoni 8 A B I U | | | 1 2 = | A

C



8.9.5.3 Repeated dose toxicity: dermal

Administrative data ^

Endpoint
A ... Remarks N ...

Type of information
A ... Other A ... Remarks N ...

Adequacy of study
A ...

Robust study summary N
 Used for classification N
 Used for SDS N

Study period
C ...

Reliability
A ... Other A ...

Rationale for reliability incl. deficiencies
C ... Other C ... Remarks N ...

Data waiving
C ...

Justification for data waiving
C

Justification for type of information
C

Attached justification	Reason / purpose
N	N

+ Add...
 ✎ Edit...
 ✕ Delete
 ↑ Move up
 ↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
 ✎ Edit...
 ✕ Delete
 ↑ Move up
 ↓ Move down
 ➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
 ✕ Delete
 ↑ Move up
 ↓ Move down
 ➤ Go to link target

Data access

N ... Other N ... Remarks N ...

Data protection claimed

N ... Remarks N ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline

A | X

A ...

GLP compliance

C ... Remarks N ...

Limit test

A ...

Test material ^

Test material information

... > 🔗 X

Specific details on test material used for the study

A | X

C ...

Test animals ^

Species

A ... Other A ...

Strain

A ... Other A ... Remarks N ...

Details on species / strain selection

C ...

Sex

A ...

Details on test animals and environmental conditions

A, X

C
...

Administration / exposure

Type of coverage

A
...
Other
A
...

Vehicle

C
...
Other
C
...
Remarks
N
...

Details on exposure

A, X

C
...

Analytical verification of doses or concentrations

C
...
Remarks
N
...

Details on analytical verification of doses or concentrations

C
...

Duration of treatment / exposure

C
...

Frequency of treatment

C
...

Doses / concentrations

Dose / conc.	Remarks
C	C

+ Add...
 ✎ Edit...
 ✕ Delete
 ↑ Move up
 ↓ Move down

No. of animals per sex per dose

C
...

Control animals

C
...

Details on study design

A, X

C
...

Positive control

C
...

Examinations ^

Observations and examinations performed and frequency

A₁ | X

C ...

Sacrifice and pathology

A₁ | X

C ...

Other examinations

C ...

Statistics

C ...

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A^v B I U [text alignment icons] [list icons] [undo/redo icons]

N

Results and discussion ^

Results of examinations ^

Clinical signs

C ...

Description (incidence and severity)

C ...

Dermal irritation

C ...

Description (incidence and severity)

C ...

Mortality

C ...

Description (incidence)

C ...

Body weight and weight changes

C ...

Description (incidence and severity)

C ...

Food consumption and compound intake (if feeding study)	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Food efficiency	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Water consumption and compound intake (if drinking water study)	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Ophthalmological findings	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Haematological findings	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Clinical biochemistry findings	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Urinalysis findings	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Behaviour (functional findings)	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...

Immunological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/>
Organ weight findings including organ / body weight ratios
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Gross pathological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Neuropathological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Histopathological findings: non-neoplastic
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Histopathological findings: neoplastic
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Other effects
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Details on results
<input type="text" value="C"/> ...

Effect levels ^

Key result	Dose descriptor	Effect level	Based on	Sex	Basis for effect level	Remarks on result
A <input type="checkbox"/>	A	A	A	A	A	A

⊕ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Target system / organ toxicity ^

Key result	Critical effects o...	Lowest effectiv...	System	Organ	Treatment related	Dose response r...	Relevant for hu...
A <input type="checkbox"/>	A	A	A	A	A	A	A

⊕ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Any other information on results incl. tables ^

Normal
Aharoni
8
A
B
I
U
≡
≡
≡
1/2
≡
≡
≡

A

Overall remarks, attachments ^

Overall remarks

Normal
Aharoni
8
A
B
I
U
≡
≡
≡
1/2
≡
≡
≡

N

Attached background material

Attached document	Remarks
N	N

⊕ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Attached full study report

N

⊕ Add...
📄 Open
✎ Properties
✕ Delete
↑ Move up
↓ Move down

Illustration (picture/graph)

N

🔍 Zoom
⊕ Load
✕ Delete

Applicant's summary and conclusion ^

Conclusions

C ...

Executive summary

Normal Aharoni 8 A B I U | | | 1/2 = | A ↻

C

8.10 Reproductive toxicity

Administrative data ^

Key value for chemical safety assessment ^

Effects on fertility ^

Description of key information ^

Normal Aharoni 8 A B I U

A

Link to relevant study records ^

Study name / type

+ Add... X Delete ↑ Move up ↓ Move down > Go to link target

Effect on fertility: via oral route ^

Endpoint conclusion
A

Dose descriptor
A

A A

Study duration
A

Species
A Other A

Quality of whole database
A

Effect on fertility: via inhalation route ^

Endpoint conclusion
A

Dose descriptor
A

A A

Study duration
A

Species
A Other A

Quality of whole database
A

Effect on fertility: via dermal route ^

Endpoint conclusion
A

Dose descriptor
A

Study duration
A

Species
A Other A

Quality of whole database
A

Additional information ^

Normal Aharoni 8 A B I U

C

Effects on developmental toxicity ^

Description of key information ^

Normal Aharoni 8 A B I U

A

Link to relevant study records ^

Study name / type

+ Add... X Delete ^ Move up v Move down > Go to link target

Effect on developmental toxicity: via oral route ^

Endpoint conclusion
A

Dose descriptor
A

Study duration
A

Species
A Other A

Quality of whole database
A

Effect on developmental toxicity: via inhalation route ^

Endpoint conclusion
A

Dose descriptor
A

Study duration
A

Species
A Other A

Quality of whole database
A

Effect on developmental toxicity: via dermal route ^

Endpoint conclusion
A

Dose descriptor
A

Study duration
A

Species
A Other A

Quality of whole database
A

Additional information ^

Normal Aharoni 8 A B I U

C

Toxicity to reproduction: other studies ^

Description of key information ^

Normal Aharoni 8 A B I U [List icons]

A

Link to relevant study records ^

Study name / type

[Empty text area]

+ Add... X Delete ↑ Move up ↓ Move down > Go to link target

Additional information ^

Normal Aharoni 8 A B I U [List icons]

C

Mode of Action Analysis / Human Relevance Framework ^

Normal Aharoni 8 A B I U [List icons]

A

Justification for classification or non-classification ^

Normal Aharoni 8 A B I U [List icons]

A

8.10.1 Pre-natal developmental toxicity study

Administrative data ^

Endpoint
 ... Remarks

Type of information
 ... Other ... Remarks

Adequacy of study

Robust study summary
 Used for classification
 Used for SDS

Study period

Reliability
 ... Other

Rationale for reliability incl. deficiencies
 ... Other ... Remarks

Data waiving

Justification for data waiving

Justification for type of information

Attached justification

Attached justification	Reason / purpose
<input type="text" value="N"/>	<input type="text" value="N"/>

+ Add... Edit... Delete Move up Move down

Cross-reference

Reason / purpose	Related information	Remarks
<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="N"/>

+ Add... Edit... Delete Move up Move down Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
<input type="text" value="B"/>	<input type="text" value="B"/>	<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="B"/>	<input type="text" value="N"/>	<input type="text" value="N"/>	<input type="text" value="A"/>	<input type="text" value="N"/>	<input type="text" value="A"/>	<input type="text" value="N"/>

+ Add... Delete Move up Move down Go to link target

Data access
N ... Other N ... Remarks N ...

Data protection claimed
N ... Remarks N ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline
A, X
A ...

GLP compliance
C ... Remarks N ...

Limit test
A ...

Test material ^

Test material information
[Text field] > 🔗 X

Specific details on test material used for the study
A, X
C ...

Test animals ^

Species
A ... Other A ...

Strain
A ... Other A ... Remarks N ...

Details on test animals and environmental conditions
A, X
C ...

Administration / exposure ^

Route of administration
 ... Other ...

Type of inhalation exposure (if applicable)
 ... Other ... Remarks ...

Vehicle
 ... Other ... Remarks ...

Mass median aerodynamic diameter (MMAD)
 ... Other ...

Geometric standard deviation (GSD)

Remarks on MMAD
 ...

Details on exposure
 ...

Analytical verification of doses or concentrations
 ... Remarks ...

Details on analytical verification of doses or concentrations
 ...

Details on mating procedure
 ...

Duration of treatment / exposure
 ...

Frequency of treatment
 ...

Duration of test
 ...

Doses / concentrations

Dose / conc.	Remarks
<input type="text" value="C"/>	<input type="text" value="C"/>

+ Add... Edit... Delete Move up Move down

No. of animals per sex per dose
 ...

Control animals

Details on study design
 ...

Examinations ^

Maternal examinations
A | X v

C ...

Ovaries and uterine content
A | X v

C ...

Fetal examinations
A | X v


C ...

Statistics
C ...

Indices
C ...

Historical control data
C ...

Any other information on materials and methods incl. tables ^



N

Results and discussion ^

Results: maternal animals ^

General toxicity (maternal animals) ^

Clinical signs
C ...

Description (incidence and severity)
C ...

Dermal irritation (if dermal study)
C ...

Description (incidence and severity)
C ...

Mortality
<input type="text" value="C"/> ... ▼
Description (incidence)
<input type="text" value="C"/> ...
Body weight and weight changes
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Food consumption and compound intake (if feeding study)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Food efficiency
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Water consumption and compound intake (if drinking water study)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Ophthalmological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Haematological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...

Clinical biochemistry findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Urinalysis findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Behaviour (functional findings)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Immunological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Organ weight findings including organ / body weight ratios
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Gross pathological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Neuropathological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Histopathological findings: non-neoplastic
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...

Histopathological findings: neoplastic
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Other effects
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Details on results
<input type="text" value="C"/> ...
Maternal developmental toxicity ^
Number of abortions
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Pre- and post-implantation loss
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Total litter losses by resorption
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Effects on pregnancy duration
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Early or late resorptions
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...

Dead fetuses

... ▾

Description (incidence and severity)

C ...

Changes in pregnancy duration

... ▾

Description (incidence and severity)

C ...

Changes in number of pregnant

... ▾

Description (incidence and severity)

C ...

Other effects

... ▾

Description (incidence and severity)

C ...

Details on maternal toxic effects

C ...

Effect levels (maternal animals) ^

Key result	Dose descriptor	Effect level	Based on	Basis for effect level	Remarks on result
A <input type="checkbox"/>	A	A	A	A	A

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Maternal abnormalities ^

Key result	Abnormalities	Localisation	Description (incidence and severity)
A <input type="checkbox"/>	A	A	A

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Results (fetuses) ^

Fetal body weight changes

... ▼

Description (incidence and severity)

...

Reduction in number of live offspring

... ▼

Description (incidence and severity)

...

Changes in sex ratio

... ▼

Description (incidence and severity)

...

Fetal/pup body weight changes

... ▼

Description (incidence and severity)

...

Changes in litter size and weights

... ▼

Description (incidence and severity)

...

Changes in postnatal survival

... ▼

Description (incidence and severity)

...

External malformations

... ▼

Description (incidence and severity)

...

Skeletal malformations

... ▼

Description (incidence and severity) C ...

Visceral malformations C ...

Description (incidence and severity) C ...

Other effects C ...

Description (incidence and severity) C ...

Details on embryotoxic / teratogenic effects C ...

Effect levels (fetuses) ^

Key result	Dose descriptor	Effect level	Based on	Sex	Basis for effect level	Remarks on result
A <input type="checkbox"/>	A	A	A	A	A	A

+ Add... Edit... Delete Move up Move down

Fetal abnormalities ^

Key result	Abnormalities	Localisation	Description (incidence and severity)
A <input type="checkbox"/>	A	A	A

+ Add... Edit... Delete Move up Move down

Overall developmental toxicity ^

Key result	Developmental effe...	Lowest effective d...	Treatment related	Relation to maternal...	Dose response rela...	Relevant for humans
A <input type="checkbox"/>	A	A	A	A	A	A

+ Add... Edit... Delete Move up Move down

Any other information on results incl. tables ^

Normal Aharoni 8 A^v B I U | | | 1 2 3 4 5 6 7 8 9 0 | A^v |

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U [List icons]

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... X Delete ↑ Move up ↓ Move down

Attached full study report

N

+ Add... Open Properties X Delete ↑ Move up ↓ Move down

Illustration (picture/graph)

N

Zoom + Load X Delete

Applicant's summary and conclusion ^

Conclusions

C ...

Executive summary

Normal Aharoni 8 A B I U [List icons]

C

8.10.2 Two-generation reproductive toxicity study

Administrative data ^

Endpoint
 ...

Type of information

Adequacy of study

Robust study summary
 Used for classification
 Used for SDS

Study period

Reliability
 ...

Rationale for reliability incl. deficiencies

Data waiving

Justification for data waiving

Justification for type of information

Attached justification

Attached justification	Reason / purpose

Cross-reference

Reason / purpose	Related information	Remarks

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks

Data access

N ... Other **N** ... Remarks **N** ...

Data protection claimed

N ... Remarks **N** ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline

A | X ...

GLP compliance

C ... Remarks **N** ...

Limit test

A ...

Justification for study design

A | X ...

C ...

Test material ^

Test material information

... > 🔗 X

Specific details on test material used for the study

A | X ...

C ...

Test animals ^

Species

A ... Other **A** ...

Strain

A ... Other **A** ... Remarks **N** ...

Details on species / strain selection

C ...

Sex

A ...

Details on test animals and environmental conditions

A | X ...

C ...

Administration / exposure ^

Route of administration
A ... Other A ...

Type of inhalation exposure (if applicable)
A ... Other A ... Remarks N ...

Mass median aerodynamic diameter (MMAD)
C C C C C ... Other C ...

Geometric standard deviation (GSD)
C

Remarks on MMAD
C ...

Vehicle
C ... Other C ... Remarks N ...

Details on exposure
A X C ...

Details on mating procedure
A X C ...

Analytical verification of doses or concentrations
C ... Remarks N ...

Details on analytical verification of doses or concentrations
C ...

Duration of treatment / exposure
C ...

Frequency of treatment
C ...

Details on study schedule
A X C ...

Doses / concentrations

Dose / conc.	Remarks
C	C

+ Add... Edit... X Delete ↑ Move up ↓ Move down

No. of animals per sex per dose	C	...
Control animals	C	
Details on study design	C	...
Positive control	C	...
Examinations ^		
Parental animals: Observations and examinations	C	...
Estrous cyclicity (parental animals)	C	...
Sperm parameters (parental animals)	C	...
Litter observations	C	...
Postmortem examinations (parental animals)	C	...
Postmortem examinations (offspring)	C	...
Statistics	C	...
Reproductive indices	C	...
Offspring viability indices	C	...

Any other information on materials and methods incl. tables ^

Rich text editor toolbar with icons for undo, redo, bold, italic, underline, text color, background color, bulleted list, numbered list, link, unlink, insert table, insert image, and others. Below the toolbar are dropdown menus for font style (Normal), font name (Aharoni), and font size (8). The editor area contains a red circle with the letter 'N'.

Results and discussion ^

Results: P0 (first parental animals) ^

General toxicity (P0) ^

Clinical signs
 ...

Description (incidence and severity)
 ...

Dermal irritation (if dermal study)
 ...

Description (incidence and severity)
 ...

Mortality
 ...

Description (incidence)
 ...

Body weight and weight changes
 ...

Description (incidence and severity)
 ...

Food consumption and compound intake (if feeding study)
 ...

Description (incidence and severity)
 ...

Food efficiency
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Water consumption and compound intake (if drinking water study)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Ophthalmological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Haematological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Clinical biochemistry findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Urinalysis findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Behaviour (functional findings)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Immunological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...

Organ weight findings including organ / body weight ratios
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Gross pathological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Neuropathological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Histopathological findings: non-neoplastic
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Histopathological findings: neoplastic
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Other effects
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Reproductive function / performance (P0) ^
Reproductive function: estrous cycle
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Reproductive function: sperm measures
<input type="text" value="C"/> ... ▼

Description (incidence and severity)
C ...

Reproductive performance
C ... ▾

Description (incidence and severity)
C ...

Details on results (P0) ^
A ...

Effect levels (P0) ^

Key result	Dose descriptor	Effect level	Based on	Sex	Basis for effect level	Remarks on result
A <input type="checkbox"/>	A	A	A	A	A	A

⊕ Add... ✎ Edit... ✕ Delete ↑ Move up ↓ Move down

Target system / organ toxicity (P0) ^

Key result	Critical effects ...	Lowest effectiv...	System	Organ	Treatment related	Dose response ...	Relevant for hu...
A <input type="checkbox"/>	A	A	A	A	A	A	A

⊕ Add... ✎ Edit... ✕ Delete ↑ Move up ↓ Move down

Results: P1 (second parental generation) ^

General toxicity (P1) ^

Clinical signs
C ... ▾

Description (incidence and severity)
C ...

Dermal irritation (if dermal study)
C ... ▾

Description (incidence and severity)
C ...

Mortality
<input type="text" value="C"/> ... ▼
Description (incidence) <input type="text" value="C"/> ...
Body weight and weight changes
<input type="text" value="C"/> ... ▼
Description (incidence and severity) <input type="text" value="C"/> ...
Food consumption and compound intake (if feeding study)
<input type="text" value="C"/> ... ▼
Description (incidence and severity) <input type="text" value="C"/> ...
Food efficiency
<input type="text" value="C"/> ... ▼
Description (incidence and severity) <input type="text" value="C"/> ...
Water consumption and compound intake (if drinking water study)
<input type="text" value="C"/> ... ▼
Description (incidence and severity) <input type="text" value="C"/> ...
Ophthalmological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity) <input type="text" value="C"/> ...
Haematological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity) <input type="text" value="C"/> ...
Clinical biochemistry findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity) <input type="text" value="C"/> ...

Urinalysis findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Behaviour (functional findings)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Immunological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Organ weight findings including organ / body weight ratios
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Gross pathological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Neuropathological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Histopathological findings: non-neoplastic
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...

Histopathological findings: neoplastic	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Other effects	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Details on results	
<input type="text" value="C"/>	...
Reproductive function / performance (P1) ^	
Reproductive function: estrous cycle	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Reproductive function: sperm measures	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...

Reproductive performance

C ... ▼

Description (incidence and severity)

C ...

Details on results (P1) ^

A ...

Effect levels (P1) ^

Key result	Dose descriptor	Effect level	Based on	Sex	Basis for effect level	Remarks on result
A	A	A	A	A	A	A

+ Add... Edit... Delete Move up Move down

Target system / organ toxicity (P1) ^

Key result	Critical effects ...	Lowest effectiv...	System	Organ	Treatment related	Dose response ...	Relevant for hu...
A	A	A	A	A	A	A	A

Results: F1 generation ^

General toxicity (F1) ^

Clinical signs

C ... ▼

Description (incidence and severity)

C ...

Dermal irritation (if dermal study)

C ... ▼

Description (incidence and severity)

C ...

Mortality / viability

C ... ▼

Description (incidence and severity)

C ...

Body weight and weight changes

C ... ▼

Description (incidence and severity)

C ...

Food consumption and compound intake (if feeding study)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Food efficiency
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Water consumption and compound intake (if drinking water study)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Ophthalmological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Haematological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Clinical biochemistry findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Urinalysis findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Sexual maturation
<input type="text" value="C"/> ... ▼

Description (incidence and severity)	
<input type="text" value="C"/>	...
Organ weight findings including organ / body weight ratios	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Gross pathological findings	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Histopathological findings	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Other effects	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Developmental neurotoxicity (F1) ^	
Behaviour (functional findings)	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Developmental immunotoxicity (F1) ^	
Developmental immunotoxicity	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...

Details on results (F1) ^

A
...

Effect levels (F1) ^

Key result	Dose descriptor	Generation	Effect level	Based on	Sex	Basis for effect ...	Remarks on result
A <input type="checkbox"/>	A	A	A	A	A	A	A

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Target system / organ toxicity (F1) ^

Key result	Critical effects ...	Lowest effectiv...	System	Organ	Treatment related	Dose response ...	Relevant for hu...
A <input type="checkbox"/>	A	A	A	A	A	A	A

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Results: F2 generation ^

General toxicity (F2) ^

Clinical signs

C
...
▼

Description (incidence and severity)

C
...

Dermal irritation (if dermal study)

C
...
▼

Description (incidence and severity)

C
...

Mortality / viability

C
...
▼

Description (incidence and severity)

C
...

Body weight and weight changes

C
...
▼

Description (incidence and severity)

C
...

Food consumption and compound intake (if feeding study)

C
...
▼

Description (incidence and severity)	
<input type="text" value="C"/>	...
Food efficiency	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Water consumption and compound intake (if drinking water study)	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Ophthalmological findings	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Haematological findings	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Clinical biochemistry findings	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Urinalysis findings	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Sexual maturation	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...

Organ weight findings including organ / body weight ratios
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Gross pathological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Histopathological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Other effects
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Developmental neurotoxicity (F2) ^
Behaviour (functional findings)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Developmental immunotoxicity (F2) ^
Developmental immunotoxicity
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Details on results (F2) ^
<input type="text" value="A"/> ...

Effect levels (F2) ^

Key result	Dose descriptor	Generation	Effect level	Based on	Sex	Basis for effect ...	Remarks on result
A <input type="checkbox"/>	A	A	A	A	A	A	A

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Target system / organ toxicity (F2) ^

Key result	Critical effects ...	Lowest effectiv...	System	Organ	Treatment related	Dose response ...	Relevant for hu...
A <input type="checkbox"/>	A	A	A	A	A	A	A

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Overall reproductive toxicity ^

Key result	Reproductive effec...	Lowest effective d...	Treatment related	Relation to other to...	Dose response rela...	Relevant for humans
A <input type="checkbox"/>	A	A	A	A	A	A

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Any other information on results incl. tables ^

Normal
Aharoni
8

A
B
I
U

A

Overall remarks, attachments ^

Overall remarks

Normal
Aharoni
8

A
B
I
U

N

Attached background material

Attached document	Remarks
N	N

Attached full study report

N

⊕ Add...
📄 Open
✎ Properties
✕ Delete
↑ Move up
↓ Move down

Illustration (picture/graph)

N

🔍 Zoom
⊕ Load
✕ Delete

Applicant's summary and conclusion ^

Conclusions

C
...

Executive summary

C

8.11 Carcinogenicity

Administrative data ^

A

Description of key information ^

A

Key value for chemical safety assessment ^

Carcinogenicity: via oral route ^

Link to relevant study records ^
 Study name / type

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Endpoint conclusion ^

Endpoint conclusion
A

Dose descriptor
A

A
A

Study duration
A

Species
A
Other A

Quality of whole database
A

System
A
Other A

Organ
A

Carcinogenicity: via inhalation route ^

Link to relevant study records ^

Study name / type

+ Add... X Delete ↑ Move up ↓ Move down > Go to link target

Endpoint conclusion ^

Endpoint conclusion

A ...

Dose descriptor

A ...

A A ...

Study duration

A ...

Species

A ... Other A ...

Quality of whole database

A ...

System

A ... Other A ...

Organ

A

Carcinogenicity: via dermal route ^

Link to relevant study records ^

Study name / type

+ Add... X Delete ↑ Move up ↓ Move down > Go to link target

Endpoint conclusion ^

Endpoint conclusion

A ...

Dose descriptor

A ...

A A ...

Study duration

A ...

Species
A ... Other A ...

Quality of whole database
A ...

System
A ... Other A ...

Organ
A

Mode of Action Analysis / Human Relevance Framework ^

Normal Aharoni 8 A B I U | | | 1 2 = | A ✎ ↻

A

Additional information ^

Normal Aharoni 8 A B I U | | | 1 2 = | A ✎ ↻

C

Justification for classification or non-classification ^

Normal Aharoni 8 A B I U | | | 1 2 = | A ✎ ↻

A

Administrative data ^

A
A

Endpoint Remarks N

Type of information Other A Remarks N

Adequacy of study

A

Robust study summary N

Used for classification N

Used for SDS N

Study period ...

C

Reliability Other A

A

Rationale for reliability incl. deficiencies Other C Remarks N

C

Data waiving ...

C

Justification for data waiving

C

Justification for type of information

C

Attached justification

Attached justification	Reason / purpose
N	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data access
 ... Other ... Remarks ...

Data protection claimed
 ... Remarks ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline
 ...

GLP compliance
 ... Remarks ...

Test material ^

Test material information
 > ∞ X

Specific details on test material used for the study
 ...

Test animals ^

Species
 ... Other ...

Strain
 ... Other ... Remarks ...

Details on species / strain selection
 ...

Sex
 ...

Details on test animals and environmental conditions
 ...

Administration / exposure ^

Route of administration
 ... Other ...

Type of inhalation exposure (if applicable)
 ... Other ... Remarks ...

Vehicle
 ... Other ... Remarks ...

Mass median aerodynamic diameter (MMAD)
 ... Other ...

Geometric standard deviation (GSD)

C

Remarks on MMAD

C ...

Details on exposure

A | **X** ...

C ...

Analytical verification of doses or concentrations

C ... **Remarks** **N** ...

Details on analytical verification of doses or concentrations

C ...

Duration of treatment / exposure

C ...

Frequency of treatment

C ...

Post exposure period

C ...

Doses / concentrations

Dose / conc.	Remarks
C	C

No. of animals per sex per dose

C ...

Control animals

C

Details on study design

A | **X** ...

C ...

Positive control

C ...

Examinations ^

Observations and examinations performed and frequency

A | **X** ...

C ...

Sacrifice and pathology
A ↘ X

C ...

Other examinations

C ...

Statistics

C ...

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A B I U | | | 1/2 = | A \$ |

N

Results and discussion ^

Results of examinations ^

Clinical signs

C ...

Description (incidence and severity)

C ...

Dermal irritation (if dermal study)

C ...

Description (incidence and severity)

C ...

Mortality

C ...

Description (incidence)

C ...

Body weight and weight changes
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Food consumption and compound intake (if feeding study)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Food efficiency
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Water consumption and compound intake (if drinking water study)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Ophthalmological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Haematological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Clinical biochemistry findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Urinalysis findings
<input type="text" value="C"/> ... ▼

Description (incidence and severity)	
<input type="text" value="C"/>	...
Behaviour (functional findings)	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Immunological findings	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Organ weight findings including organ / body weight ratios	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Gross pathological findings	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Neuropathological findings	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Histopathological findings: non-neoplastic	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...
Histopathological findings: neoplastic	
<input type="text" value="C"/>	...
Description (incidence and severity)	
<input type="text" value="C"/>	...

Other effects

C ...

Description (incidence and severity)

C ...

Details on results

A ...

Relevance of carcinogenic effects / potential

A ...

Effect levels ^

Key result	Dose descriptor	Effect level	Based on	Sex	Basis for effect level	Remarks on result
A <input type="checkbox"/>	A	A	A	A	A	A

+ Add... Edit... Delete Move up Move down

Target system / organ toxicity ^

Key result	Critical effects o...	Lowest effectiv...	System	Organ	Treatment related	Dose response r...	Relevant for hu...
A <input type="checkbox"/>	A	A	A	A	A	A	A

+ Add... Edit... Delete Move up Move down


Any other information on results incl. tables ^

Normal Aharoni 8 A^v B I U ...

A

Overall remarks, attachments ^

Overall remarks



N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... X Delete ↑ Move up ↓ Move down

Attached full study report

N

+ Add... Open Properties X Delete ↑ Move up ↓ Move down

Illustration (picture/graph)

N


Q Zoom + Load X Delete

Applicant's summary and conclusion ^

Conclusions

C ...

Executive summary



C

8.12 Relevant health data, observations and treatments

Administrative data ^

A

Description of key information ^

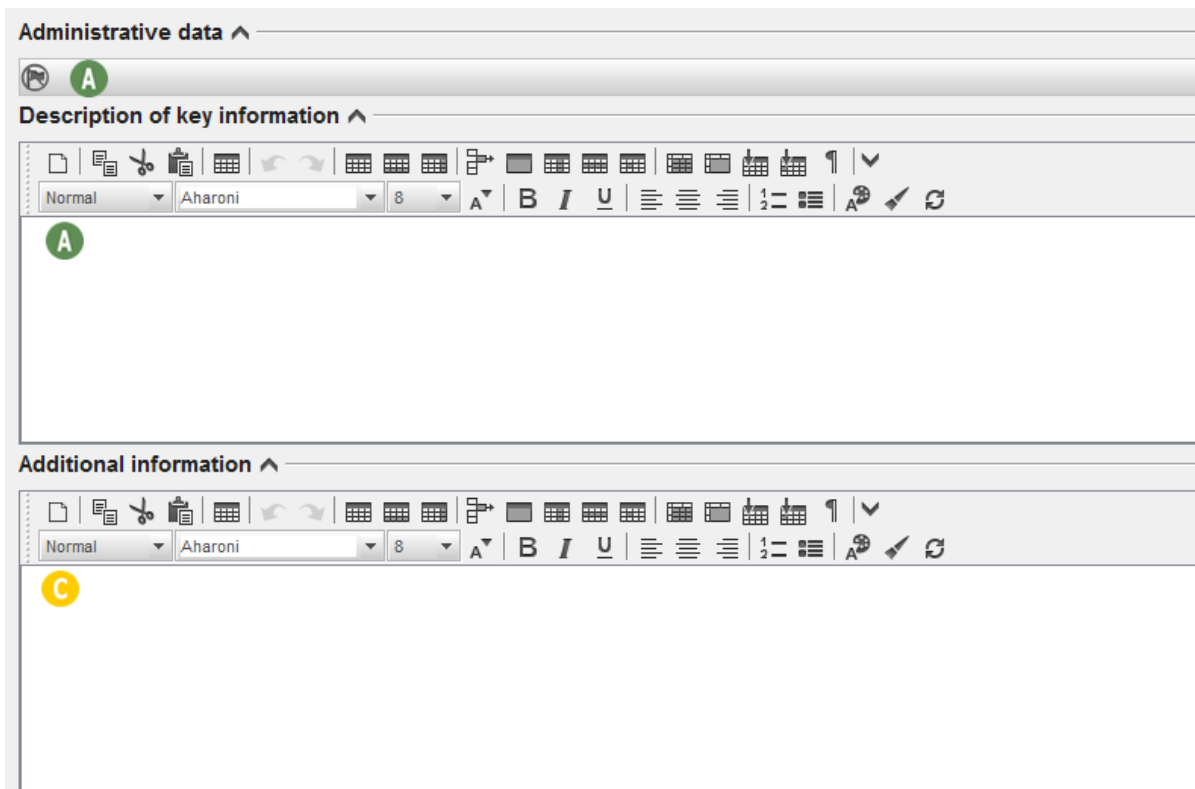
Normal Aharoni 8 A B I U | | | 1 2 = | A

A

Additional information ^

Normal Aharoni 8 A B I U | | | 1 2 = | A

C



8.12.1 Medical surveillance data on manufacturing plant personnel

Administrative data ^

A

Endpoint
A ... Remarks N ...

Type of information
A ... Other A ... Remarks N ...

Adequacy of study
A ...

Robust study summary N
 Used for classification N
 Used for SDS N

Study period
C ...

Reliability
A ... Other A ...

Rationale for reliability incl. deficiencies
C ... Other C ... Remarks N ...

Data waiving
C ...

Justification for data waiving
C

Justification for type of information
C

Attached justification	Reason / purpose
N	N

+ Add...
 ✎ Edit...
 ✕ Delete
 ↑ Move up
 ↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
 ✎ Edit...
 ✕ Delete
 ↑ Move up
 ↓ Move down
 ➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
 ✕ Delete
 ↑ Move up
 ↓ Move down
 ➤ Go to link target

Data access

N ... Other N ... Remarks N ...

Data protection claimed

N ... Remarks N ...

Materials and methods ^

Study type

A ... Other A ... Remarks N ...

Endpoint addressed

A

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline

A | X

A ...

GLP compliance

C ... Remarks N ...

Test material ^

Test material information

[Text field] > 🔗 X

Specific details on test material used for the study

A | X

C ...

Method ^

Type of population

Ethical approval
 Remarks

Details on study design

Any other information on materials and methods incl. tables ^

Results and discussion ^

Results

Any other information on results incl. tables ^

Overall remarks, attachments ^

Overall remarks

Attached background material

Attached document	Remarks
<input type="button" value="N"/>	<input type="button" value="N"/>

Attached full study report

N

+ Add... Open Properties Delete Move up Move down

Illustration (picture/graph)

N

Zoom Load Delete

Applicant's summary and conclusion ^

Conclusions

C

Executive summary

Normal Aharoni 8 A B I U | | | 1/2 | A ↻

C

8.12.2 Direct observations: clinical cases, poisoning incidents and other

Administrative data ^

A

Endpoint

A
Remarks N

Type of information

A
Other A
Remarks N

Adequacy of study

A

Robust study summary N

Used for classification N

Used for SDS N

Study period

C

Reliability

A
Other A

Rationale for reliability incl. deficiencies

C
Other C
Remarks N

Data waiving

C

Justification for data waiving

C

Justification for type of information

C

Attached justification

Attached justification	Reason / purpose
N	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data access
[N] ... Other [N] ... Remarks [N] ...

Data protection claimed
[N] ... Remarks [N] ...

Materials and methods ^

Study type
[A] ... Other [A] ... Remarks [N] ...

Endpoint addressed
[A]

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
[A]	[A]	[A]	[A]

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline
[A] X

GLP compliance
[C] ... Remarks [N] ...

Test material ^

Test material information
[] > 🔗 X

Specific details on test material used for the study
[C] X

Method ^

Type of population
[A]

Subjects
[C] X

Ethical approval
[A] ... Other [A] ... Remarks [N] ...

Route of exposure
[A]

Reason of exposure
[A] ... Other [A] ...

Exposure assessment
[A] ... Remarks [N] ...

Details on exposure
[C] ...

Examinations
A₂ | X

C

Medical treatment
C

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A^v B I U

N

Results and discussion ^

Clinical signs
A

Results of examinations
A₂ | X

A

Effectivity of medical treatment
A

Outcome of incidence
A

Any other information on results incl. tables ^

Normal Aharoni 8 A^v B I U

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U | | | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... X Delete ↑ Move up ↓ Move down

Attached full study report

N

+ Add... Open Properties X Delete ↑ Move up ↓ Move down

Illustration (picture/graph)

N

Zoom + Load X Delete

Applicant's summary and conclusion ^

Conclusions

C ...


Executive summary

Normal Aharoni 8 A B I U | | | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100



C

8.12.4 Epidemiological data




Administrative data ^




Endpoint


 ... Remarks 


Type of information


 ... Other  Remarks 

Adequacy of study


 ...

Robust study summary 



Used for classification 

Used for SDS 




Study period

 ...


Reliability

 ... Other 


Rationale for reliability incl. deficiencies

 ... Other  Remarks 


Data waiving

 ...



Justification for data waiving



Justification for type of information






Attached justification

Attached justification	Reason / purpose
	

+ Add...
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↑ Move up
↓ Move down












Cross-reference

Reason / purpose	Related information	Remarks
		

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
										

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data access

N ... Other **N** ... Remarks **N** ...

Data protection claimed

N ... Remarks **N** ...

Materials and methods ^

Study type

A ... Other **A** ... Remarks **N** ...

Endpoint addressed

A

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline

A | X

GLP compliance

C ... Remarks **N** ...

Test material ^

Test material information

> 🔗 X

Specific details on test material used for the study

A | X

C ...

Method ^

Type of population

A

Ethical approval

A ... Other **A** ... Remarks **N** ...

Details on study design

A | X

C ...

Exposure assessment

A ... Remarks **N** ...

Details on exposure

A | X

C ...

Statistical methods

A

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A B I U

N

Results and discussion ^

Results

A X

A

Confounding factors

A

Strengths and weaknesses

A

Any other information on results incl. tables ^

Normal Aharoni 8 A B I U

A

Overall remarks, attachments ^

Overall remarks

[Rich text editor toolbar with icons for undo, redo, bold, italic, underline, list, link, unlink, etc.]

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... Delete Move up Move down

Attached full study report

N

+ Add... Open Properties Delete Move up Move down

Illustration (picture/graph)

N

Zoom Load Delete

Applicant's summary and conclusion ^

Conclusions

C


Executive summary

[Rich text editor toolbar with icons for undo, redo, bold, italic, underline, list, link, unlink, etc.]

C

8.12.6 Sensitisation data (humans)

Administrative data ^



Endpoint
 ... Remarks

Type of information
 ... Other ... Remarks

Adequacy of study

Robust study summary
 Used for classification
 Used for SDS

Study period

Reliability
 ... Other

Rationale for reliability incl. deficiencies
 ... Other ... Remarks

Data waiving

Justification for data waiving

Justification for type of information

Attached justification	Reason / purpose
<input type="text" value="N"/>	<input type="text" value="N"/>

Cross-reference

Reason / purpose	Related information	Remarks
<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="N"/>

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
<input type="text" value="B"/>	<input type="text" value="B"/>	<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="B"/>	<input type="text" value="N"/>	<input type="text" value="N"/>	<input type="text" value="A"/>	<input type="text" value="N"/>	<input type="text" value="A"/>	<input type="text" value="N"/>

Data access
 ... Other ... Remarks ...

Data protection claimed
 ... Remarks ...

Materials and methods ^

Type of sensitisation studied

Study type
 ... Other ... Remarks ...

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="A"/>

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline
 X

GLP compliance
 ... Remarks ...

Test material ^

Test material information
 > 🔗 X

Specific details on test material used for the study
 X

Method ^

Type of population

Ethical approval
 ... Other ... Remarks ...

Subjects
 X

Clinical history
 X

Controls

Route of administration
 ... Other ...

Details on study design

C
A, X
▼

Any other information on materials and methods incl. tables ^

N

Results and discussion ^

Results of examinations

A
A, X
▼

Any other information on results incl. tables ^

A

Overall remarks, attachments ^

Overall remarks

N

Attached background material

Attached document	Remarks
N	N

⊕ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Attached full study report

N

⊕ Add...
📄 Open
✎ Properties
✕ Delete
↑ Move up
↓ Move down

Illustration (picture/graph)

N

🔍 Zoom
⊕ Load
✕ Delete

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Applicant's summary and conclusion ^

Conclusions

C ...

Executive summary

Normal Aharoni 8 A B I U | | | 1 2 = | A ✓ ↺

C

Endpoint conclusion ^

Endpoint conclusion
A

Dose descriptor
A

A A

Study duration
A

Species
A Other A

Quality of whole database
A

Effect on neurotoxicity: via dermal route ^

Link to relevant study records ^

Study name / type

+ Add... X Delete ↑ Move up ↓ Move down > Go to link target

Endpoint conclusion ^

Endpoint conclusion
A

Dose descriptor
A

A A

Study duration
A

Species
A Other A

Quality of whole database
A

Mode of Action Analysis / Human Relevance Framework ^

Normal Aharoni 8 A B I U

A

Additional information ^

Normal Aharoni 8 A B I U

C

Justification for classification or non-classification ^

Normal Aharoni 8 A B I U

A

Administrative data ^

A

Endpoint A Remarks N

Type of information A Other A Remarks N

Adequacy of study A

Robust study summary N

Used for classification N

Used for SDS N

Study period C

Reliability A Other A

Rationale for reliability incl. deficiencies C Other C Remarks N

Data waiving C

Justification for data waiving C

Justification for type of information C

Attached justification	Reason / purpose
N	N

+ Add... Edit... Delete Move up Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data access

N	...	Other	N	Remarks	N
---	-----	-------	---	---------	---

Data protection claimed

N	...	Remarks	N
---	-----	---------	---

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Principles of method if other than guideline

A | ✕ ▼

A ...

GLP compliance

C	...	Remarks	N
---	-----	---------	---

Limit test

A	...
---	-----

Test material ^

Test material information

➤ 🔗 ✕

Specific details on test material used for the study

A | ✕ ▼

C ...

Test animals ^

Species ... A ...

Strain ... A ... N ...

Sex ...

Details on test animals and environmental conditions

| ^

...

Administration / exposure ^

Route of administration ... A ...

Vehicle ... C ... N ...

Mass median aerodynamic diameter (MMAD)

... C ...

Geometric standard deviation (GSD)

Remarks on MMAD

...

Details on exposure

| ^

...

Analytical verification of doses or concentrations

... N ...

Details on analytical verification of doses or concentrations

...

Duration of treatment / exposure

...

Frequency of treatment

...

Doses / concentrations

Dose / conc.	Remarks
<input type="text" value="C"/>	<input type="text" value="C"/>

No. of animals per sex per dose	C	...
Control animals	C	
Details on study design	A X	▼
	C	...
Examinations ^		
Observations and clinical examinations performed and frequency	A X	▼
	C	...
Specific biochemical examinations	A X	▼
	C	...
Neurobehavioural examinations performed and frequency	A X	▼
	C	...
Sacrifice and (histo)pathology	A X	▼
	C	...
Other examinations	C	...
Positive control	C	...
Statistics	C	...

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A B I U | | | 1/2 = | A |

N

Results and discussion ^

Results of examinations ^

Clinical signs
C ...

Description (incidence and severity)
C ...

Dermal irritation (if dermal study)
C ...

Description (incidence and severity)
C ...

Mortality
C ...

Description (incidence)
C ...

Body weight and weight changes
C ...

Description (incidence and severity)
C ...

Food consumption and compound intake (if feeding study)
C ...

Description (incidence and severity)
C ...

Food efficiency
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Water consumption and compound intake (if drinking water study)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Ophthalmological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Haematological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Clinical biochemistry findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Urinalysis findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Behaviour (functional findings)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Immunological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...

Organ weight findings including organ / body weight ratios

C ... ▼

Description (incidence and severity)

C ...

Gross pathological findings

C ... ▼

Description (incidence and severity)

C ...

Neuropathological findings

C ... ▼

Description (incidence and severity)

C ...

Histopathological findings: non-neoplastic

C ... ▼

Description (incidence and severity)

C ...

Histopathological findings: neoplastic

C ... ▼

Description (incidence and severity)

C ...

Other effects

C ... ▼

Description (incidence and severity)

C ...

Details on results

A ...

Effect levels ^

Key result	Dose descriptor	Effect level	Based on	Sex	Basis for effect level	Remarks on result
A <input type="checkbox"/>	A	A	A	A	A	A

Target system / organ toxicity ^

Key result	Critical effects o...	Lowest effectiv...	System	Organ	Treatment related	Dose response r...	Relevant for hu...
A	A	A	A	A	A	A	A

+ Add... Edit... Delete Move up Move down

Any other information on results incl. tables ^

Normal Aharoni 8 A B I U ...

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U ...

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... Delete Move up Move down

Attached full study report

N

+ Add... Open Properties Delete Move up Move down

Illustration (picture/graph)

N

Zoom Load Delete

Applicant's summary and conclusion ^

Conclusions

C ...

Executive summary

Normal Aharoni 8 A B I U ...

C

8.13.4 Immunotoxicity

Administrative data ^

Description of key information ^

Normal Aharoni 8 A B I U

Key value for chemical safety assessment ^

Effect on immunotoxicity: via oral route ^

Link to relevant study records ^

Study name / type

⊕ Add... ✕ Delete ↑ Move up ↓ Move down > Go to link target

Endpoint conclusion ^

Endpoint conclusion A

Dose descriptor A

Study duration A

Species A Other A

Quality of whole database A

Effect on immunotoxicity: via inhalation route ^

Link to relevant study records ^

Study name / type

⊕ Add... ✕ Delete ↑ Move up ↓ Move down > Go to link target

Endpoint conclusion ^

Endpoint conclusion
A

Dose descriptor
A

A A

Study duration
A

Species
A Other A

Quality of whole database
A

Effect on immunotoxicity: via dermal route ^

Link to relevant study records ^

Study name / type

+ Add... X Delete ↑ Move up ↓ Move down > Go to link target

Endpoint conclusion ^

Endpoint conclusion
A

Dose descriptor
A

A A

Study duration
A

Species
A Other A

Quality of whole database
A

Mode of Action Analysis / Human Relevance Framework ^

Normal Aharoni 8 A B I U

A

Additional information ^

Normal Aharoni 8 A B I U

C

Justification for classification or non-classification ^

Normal Aharoni 8 A B I U

A

Administrative data ^

Endpoint
 ... Remarks

Type of information
 ... Other ... Remarks

Adequacy of study
 ...
 Robust study summary
 Used for classification
 Used for SDS

Study period

Reliability
 ... Other

Rationale for reliability incl. deficiencies
 ... Other ... Remarks

Data waiving

Justification for data waiving

Justification for type of information

Attached justification

Attached justification	Reason / purpose
<input type="text" value="N"/>	<input type="text" value="N"/>

+ Add... Edit... Delete Move up Move down

Cross-reference

Reason / purpose	Related information	Remarks
<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="N"/>

+ Add... Edit... Delete Move up Move down Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
<input type="text" value="B"/>	<input type="text" value="B"/>	<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="B"/>	<input type="text" value="N"/>	<input type="text" value="N"/>	<input type="text" value="A"/>	<input type="text" value="N"/>	<input type="text" value="A"/>	<input type="text" value="N"/>

+ Add... Delete Move up Move down Go to link target

Data access
 ... Other ... Remarks

Data protection claimed
 ... Remarks

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

Principles of method if other than guideline

A | X

A

GLP compliance

C ... Remarks N

Limit test

A

Test material ^

Test material information

Specific details on test material used for the study

A | X

C

Test animals ^

Species

A ... Other A

Strain

A ... Other A ... Remarks N

Sex

A

Details on test animals and environmental conditions

A | X

C

Administration / exposure ^

Route of administration

A ... Other A

Vehicle

C ... Other C ... Remarks N

Mass median aerodynamic diameter (MMAD)

C C C C C ... Other C

Geometric standard deviation (GSD)

C

Remarks on MMAD

C

Details on exposure

A | X

C

Analytical verification of doses or concentrations

C ... Remarks N ...

Details on analytical verification of doses or concentrations

C ...

Duration of treatment / exposure

C ...

Frequency of treatment

C ...

Doses / concentrations

Dose / conc.	Remarks
C	C

+ Add...
✎ Edit...
✖ Delete
↑ Move up
↓ Move down

No. of animals per sex per dose

C ...

Control animals

▼ C

Details on study design

A_→ | ✖ ...

C ...

Examinations ^

Observations and clinical examinations performed and frequency

A_→ | ✖ ...

C ...

Sacrifice and pathology

A_→ | ✖ ...

C ...

Cell viabilities

A_→ | ✖ ...

C ...

Humoral immunity examinations

A_→ | ✖ ...

C ...

Specific cell-mediated immunity

A_→ | ✖ ...

C ...

Non-specific cell-mediated immunity
A₂ | X

C

Other functional activity assays
A₂ | X

C

Other examinations
C

Positive control
C

Statistics
C

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A^v B I U

N

Results and discussion ^

Results of examinations ^

Clinical signs
C

Description (incidence and severity)
C

Dermal irritation (if dermal study)
C

Description (incidence and severity)
C

Mortality
<input type="text" value="C"/> ... ▼
Description (incidence)
<input type="text" value="C"/> ...
Body weight and weight changes
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Food consumption and compound intake (if feeding study)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Food efficiency
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Water consumption and compound intake (if drinking water study)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Ophthalmological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Haematological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...

Clinical biochemistry findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Urinalysis findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Behaviour (functional findings)
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Immunological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Organ weight findings including organ / body weight ratios
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Gross pathological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...
Neuropathological findings
<input type="text" value="C"/> ... ▼
Description (incidence and severity)
<input type="text" value="C"/> ...

Histopathological findings: non-neoplastic
 ... ▾
Description (incidence and severity)
 ...

Histopathological findings: neoplastic
 ... ▾
Description (incidence and severity)
 ...

Other effects
 ... ▾
Description (incidence and severity)
 ...

Details on results
 ...

Specific immunotoxic examinations ▲

Cell viabilities
 ... ▾
Description (incidence and severity)
 ...

Humoral immunity examinations
 ... ▾
Description (incidence and severity)
 ...

Specific cell-mediated immunity
 ... ▾
Description (incidence and severity)
 ...

Non-specific cell-mediated immunity
 ... ▾
Description (incidence and severity)
 ...

Other functional activity assays
 ... ▾
Description (incidence and severity)
 ...

Other findings

C

Description (incidence and severity)

C

Effect levels ^

Key result	Dose descriptor	Effect level	Based on	Sex	Basis for effect level	Remarks on result
A <input type="checkbox"/>	A	A	A	A	A	A

+ Add... Edit... Delete Move up Move down

Target system / organ toxicity ^

Key result	Critical effects o...	Lowest effectiv...	System	Organ	Treatment related	Dose response r...	Relevant for hu...
A <input type="checkbox"/>	A	A	A	A	A	A	A

+ Add... Edit... Delete Move up Move down

Any other information on results incl. tables ^

A

Overall remarks, attachments ^

Overall remarks

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... Delete Move up Move down

8.13.6 Specific investigations

Administrative data ^

A

Link to relevant study record(s) ^

Study name / type

+ Add...
X Delete
↑ Move up
↓ Move down
> Go to link target

Description of key information ^

A

Additional information ^

C

Administrative data ^

A

Endpoint

A ... Remarks **N** ...

Type of information

A ... Other **A** ... Remarks **N** ...

Adequacy of study

A ...

Robust study summary **N**
 Used for classification **N**
 Used for SDS **N**

Study period
C ...

Reliability
A ... Other A ...

Rationale for reliability incl. deficiencies
C ... Other C ... Remarks N ...

Data waiving
C ...

Justification for data waiving
C

Justification for type of information
C ...

Attached justification

Attached justification	Reason / purpose
N	N

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Data access
N ... Other N ... Remarks N ...

Data protection claimed
N ... Remarks N ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

Principles of method if other than guideline

A | X

A

GLP compliance

C ... Remarks N

Type of method

A ... Other A ... Remarks N

Endpoint addressed

A

Test material ^

Test material information

Specific details on test material used for the study

A | X

C

Test animals ^

Species

A ... Other A

Strain

A ... Other A ... Remarks N

Sex

A

Details on test animals and environmental conditions

A | X

C

Administration / exposure ^

Route of administration

A ... Other A

Vehicle

C ... Other C ... Remarks N

Details on exposure

A | X

C

Analytical verification of doses or concentrations

C ... Remarks N

Details on analytical verification of doses or concentrations

C

Any other information on results incl. tables ^

Normal Aharoni 8 A B I U [List icons]

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U [List icons]

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... Delete Move up Move down

Attached full study report

N

+ Add... Open Properties Delete Move up Move down

Illustration (picture/graph)

N

Zoom Load Delete

Applicant's summary and conclusion ^

Conclusions

C ...

Executive summary

Normal Aharoni 8 A B I U [List icons]

C

8.14 Studies related to the exposure of humans to the active substance

Administrative data ^

Endpoint Remarks **N**

Type of information Other **A** Remarks **N**

Adequacy of study

Robust study summary **N**

Used for classification **N**

Used for SDS **N**

Study period **C**

Reliability Other **A**

Rationale for reliability incl. deficiencies Other **C** Remarks **N**

Data waiving **C**

Justification for data waiving **C**

Justification for type of information **C**

Attached justification	Reason / purpose
N	N

+ Add... Edit... X Delete ↑ Move up ↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add... Edit... X Delete ↑ Move up ↓ Move down > Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add... X Delete ↑ Move up ↓ Move down > Go to link target

Data access
N ... Other N ... Remarks N ...

Data protection claimed
N ... Remarks N ...

Materials and methods ^

Type of study / information
A ...

Endpoint addressed
A

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline
A X

GLP compliance
C ... Remarks N ...

Test material ^

Test material information
> 🔗 X

Specific details on test material used for the study
A X

Any other information on results incl. tables ^

Normal Aharoni 8 A B I U | | | 1/2 = | A ✎ ↻

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U | | | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100

N

Attached background material

Attached document	Remarks
N	N

Attached full study report

N

+ Add... Open Properties Delete Move up Move down

Illustration (picture/graph)

N

Zoom Load Delete

Applicant's summary and conclusion ^

Conclusions

C

Executive summary

Normal Aharoni 8 A B I U | | | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100

C

8.15 Toxic effects on livestock and pets

Administrative data ^

Description of key information ^

Normal Aharoni 8 A B I U

Additional information ^

Normal Aharoni 8 A B I U

Administrative data ^

Endpoint A Remarks N

Type of information A Other A Remarks N

Adequacy of study A

Robust study summary N

Used for classification N

Used for SDS N

Study period C

Reliability A Other A

Rationale for reliability incl. deficiencies C Other C Remarks N

Data waiving

C ...

Justification for data waiving

C

Justification for type of information

C ...

Attached justification

Attached justification	Reason / purpose
N	N

+ Add... Edit... Delete Move up Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add... Edit... Delete Move up Move down Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add... Delete Move up Move down Go to link target

Data access

N ... Other N ... Remarks N ...

Data protection claimed

N ... Remarks N ...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline

A ...

GLP compliance

C ... Remarks N ...

Limit test

A

Test material ^

Test material information

Specific details on test material used for the study

A | X

C

Test animals ^

Species

A Other **A**

Sex

A

Details on test animals and environmental conditions

A | X

C

Administration / exposure ^

Route of exposure

A Other **A** Remarks **N**

Vehicle

C Other **C** Remarks **N**

Details on exposure

A | X

C

Analytical verification of doses or concentrations

C Remarks **N**

Details on analytical verification of doses or concentrations

C

Duration of treatment / exposure

C

Frequency of treatment

C

Post exposure period

C

Doses / concentrations

Dose / conc.	Remarks
C	C

+ Add... Edit... X Delete ↑ Move up ↓ Move down

No. of animals per sex per dose	
C	...
Control animals	
C	
Further details on study design	
A ₂ X	▼
C	...
Examinations ^	
Observations and examinations performed and frequency	
A ₂ X	▼
C	...
Sacrifice and pathology	
A ₂ X	▼
C	...
Other examinations	
C	...
Statistics	
C	...
Any other information on materials and methods incl. tables ^	
N	
Results and discussion ^	
Clinical signs and mortality	
A	Remarks A
A	Remarks A
Body weight and weight gain	
A	Remarks A
Food consumption and compound intake (if feeding study)	
A	Remarks A
Water consumption and compound intake (if drinking water study)	
C	Remarks C
Haematology	
C	Remarks C
Clinical chemistry	
C	Remarks C

Urinalysis

C Remarks C

Gross pathology and organ weights

C Remarks C

Histopathology

C Remarks C

Details on results

A

Any other information on results incl. tables

A

Overall remarks, attachments

Overall remarks

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... Delete Move up Move down

Attached full study report

N

+ Add... Open Properties Delete Move up Move down

Illustration (picture/graph)

N

Zoom Load Delete

Applicant's summary and conclusion ^

Conclusions

C ...

Executive summary

Normal Aharoni 8 A B I U [list icons]

C

8.16 Food and feeding stuffs studies including for food-producing animals and their products

Administrative data ^

A

Description of key information ^

Normal Aharoni 8 A B I U

A

Additional information ^

Normal Aharoni 8 A B I U

C

8.16.1 Proposed acceptable residue levels

Administrative data ^

Endpoint
A ... **Remarks** N ...

Type of information
A ... **Other** A ... **Remarks** N ...

Adequacy of study
A ...

Robust study summary N
 Used for classification N
 Used for SDS N

Study period
C ...

Reliability
A ... **Other** A ...

Rationale for reliability incl. deficiencies
C ... **Other** C ... **Remarks** N ...

Data waiving
C ...

Justification for data waiving
C

Justification for type of information
C

Attached justification

Attached justification	Reason / purpose
N	N

+ Add... Edit... Delete Move up Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add... Edit... Delete Move up Move down Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add... Delete Move up Move down Go to link target

Data access

N ... Other **N** ... Remarks **N** ...

Data protection claimed

N ... Remarks **N** ...

Materials and methods ^

Background information

C ...

Product type

A ... Other **A** ...

Type of study

A ... Other **A** ...

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

⊕ Add... ✎ Edit... ✕ Delete ↑ Move up ↓ Move down

Principles of method if other than guideline

A | ✕ ...

GLP compliance

C ... Remarks **N** ...

Materials and methods ^

Background information

C ...

Product type

A ... Other **A** ...

Type of study

A ... Other **A** ...

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

⊕ Add... ✎ Edit... ✕ Delete ↑ Move up ↓ Move down

Principles of method if other than guideline

A | ✕ ...

GLP compliance

C ... Remarks **N** ...

Administration / exposure ^

Treatment type (route of exposure)
A

Duration and frequency of dosing
C ...

Doses / concentrations
C ...

Details on dosing
A, X
C ...

No. of animals per dose group
C ...

Control animals
C

Further details on study design
C ...

Details on sampling and analytical methods
A, X
C ...

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A B I U | | | 1/2 = | A

N

Results and discussion ^

Storage stability
A ...

Distribution of residues
A ...

Recoveries
C ...

Any other information on results incl. tables ^

Normal Aharoni 8 A B I U [List icons]

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U [List icons]

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... X Delete ↑ Move up ↓ Move down

Attached full study report

N

+ Add... Open Properties X Delete ↑ Move up ↓ Move down

Illustration (picture/graph)

N

Zoom + Load X Delete

Applicant's summary and conclusion ^

Conclusions

C ...

Executive summary

Normal Aharoni 8 A B I U [List icons]

C

8.16.2 Behaviour of the residue of the active substance on the treated or contaminated food or feeding stuffs

Administrative data ^

Endpoint
A ... Remarks N ...

Type of information
A ... Other A ... Remarks N ...

Adequacy of study
A ...
 Robust study summary N
 Used for classification N
 Used for SDS N

Study period
C ...

Reliability
A ... Other A ...

Rationale for reliability incl. deficiencies
C ... Other C ... Remarks N ...

Data waiving
C ...

Justification for data waiving
C

Justification for type of information
C

Attached justification

Attached justification	Reason / purpose
N	N

+ Add... Edit... Delete Move up Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add... Edit... Delete Move up Move down Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add... Delete Move up Move down Go to link target

Data access
N ... Other N ... Remarks N ...

Data protection claimed
N ... Remarks N ...

Materials and methods ^

Background information
C ...

Product type
A ... Other A ...

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline
A | X

A ...

GLP compliance
C ... Remarks N ...

Test material ^

Test material information
[Text area]

Specific details on test material used for the study
A | X

C ...

Radiolabelling
A ... Other A ... Remarks N ...

Study design ^

Further details on study design
C ...

Any other information on materials and methods incl. tables ^

[Rich text editor toolbar: Normal, Aharoni, 8, A, B, I, U, list, link, unlink, undo, redo, print, save]

N

8.16.4 Estimation of potential or actual exposure of humans to the active substance and residues through diet and other means (also in Biocidal Product under 8.10 Other test(s) related to the exposure to humans)

NB: Biocidal Product A → C

Administrative data ^

A

Endpoint A Remarks N

Type of information A Other A Remarks N

Adequacy of study A

Robust study summary N

Used for classification N

Used for SDS N

Study period C

Reliability A Other A

Rationale for reliability incl. deficiencies C Other C Remarks N

Data waiving C

Justification for data waiving C

Justification for type of information C

Attached justification

Attached justification	Reason / purpose
N	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down
➔ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

Data access
N ... Other N ... Remarks N ...

Data protection claimed
N ... Remarks N ...

Materials and methods ^

Background information
C ...

Product type
A ... Other A ...

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline
A X
A ...

GLP compliance
C ... Remarks N ...

Test material ^

Test material information
[Text field] > ∞ X

Specific details on test material used for the study
A X
C ...

Study design ^

Further details on study design
C ...

Any other information on materials and methods incl. tables ^

[Rich text editor toolbar: Normal, Aharoni, 8, A, B, I, U, list, link, unlink, undo, redo]
N

Results and discussion ^

Details on results

A

Any other information on results incl. tables ^

Normal Aharoni 8 A B I U | | | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U | | | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... Delete Move up Move down

Attached full study report

N

+ Add... Open Properties Delete Move up Move down

Illustration (picture/graph)

N

Zoom Load Delete

Applicant's summary and conclusion ^

Conclusions

C

Executive summary

Normal Aharoni 8 A B I U | | | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100

C

8.16.5 Feeding and metabolism studies in livestock (also in Biocidal Product under 8.8 Food and feeding stuffs studies)

NB: Biocidal Product **A** → **C**

Administrative data ^

Endpoint
 ... Remarks **N** ...

Type of information
 ... Other **A** ... Remarks **N** ...

Adequacy of study
 ...
 Robust study summary **N**
 Used for classification **N**
 Used for SDS **N**

Study period
 ...

Reliability
 ... Other **A** ...

Rationale for reliability incl. deficiencies
 ... Other **C** ... Remarks **N** ...

Data waiving
 ...

Justification for data waiving

Justification for type of information

Attached justification

Attached justification	Reason / purpose
N	N

+ Add... Edit... Delete Move up Move down

Cross-reference

Reason / purpose	Related information	Remarks
A	A	N

+ Add... Edit... Delete Move up Move down Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

+ Add... Delete Move up Move down Go to link target

Data access

N ... Other **N** ... Remarks **N** ...

Data protection claimed

N ... Remarks **N** ...

Materials and methods ^

Background information

C ...

Product type

A ... Other **A** ...

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline

A | X

A ...

GLP compliance

C ... Remarks **N** ...

Test material ^

Test material information

... > 🔗 X

Specific details on test material used for the study

A | X

C ...

Radiolabelling

A ... Other **A** ... Remarks **N** ...

Test animals ^

Species

A

Details on housing conditions and test animals

A | X

C ...

Details on dietary regime

A | X

C ...

Administration / exposure ^

Route of administration
A ... Other A ...

Dosing
C ...

Details on dosing
A, X ...

No. of animals per dose group
C ...

Further details on study design
C ...

Details on sampling and analytical methods
A, X ...

N ...

Results and discussion ^

Storage stability
A ...

Total radioactive residues (TRRs)
A ...

Distribution of residues
A ...

Characterisation and identification of residues
A ...

Metabolic pathway
A ...

Any other information on results incl. tables ^

Normal Aharoni 8 A^v B I U ...

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U [List icons]

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... X Delete ↑ Move up ↓ Move down

Attached full study report

N

+ Add... Open Properties X Delete ↑ Move up ↓ Move down

Illustration (picture/graph)

N

Zoom + Load X Delete

Applicant's summary and conclusion ^

Conclusions

C ...

Executive summary

Normal Aharoni 8 A B I U [List icons]

C

8.16.6 Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the active substance (*also in Biocidal Product under 8.9 Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product*)

NB: Biocidal Product A → C

Administrative data ^

A

Endpoint A N

Type of information A Other A N

Adequacy of study A

Robust study summary N

Used for classification N

Used for SDS N

Study period C

Reliability A Other A

Rationale for reliability incl. deficiencies C Other C N

Data waiving C

Justification for data waiving C

Justification for type of information C

Attached justification	Reason / purpose
N	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Reason / purpose	Related information	Remarks
A	A	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down
➔ Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
B	B	A	A	B	N	N	A	N	A	N

Data access

N ... Other **N** ... Remarks **N** ...

Data protection claimed

N ... Remarks **N** ...

Materials and methods ^

Background information

C ...

Product type

A ... Other **A** ...

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add... Edit... Delete Move up Move down

Principles of method if other than guideline

A | X

A ...

GLP compliance

C ... Remarks **N** ...

Test material ^

Test material information

... > ∞ X

Specific details on test material used for the study

A | X

C ...

Study design ^

Details on study design

C ...

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A[^] B I U ...

N

Results and discussion ^

Details on results

A

Any other information on results incl. tables ^

Normal Aharoni 8 A B I U

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... X Delete Move up Move down

Attached full study report

N

+ Add... Open Properties X Delete Move up Move down

Illustration (picture/graph)

N

Zoom Load Delete

Applicant's summary and conclusion ^

Conclusions



C

Executive summary

Normal Aharoni 8 A B I U

C

8.17 Tests to assess toxic effects of metabolites from treated plants *(also in Biocidal Product under 8.7.1 Other endpoints)*

NB: Biocidal Product  → 


Administrative data ^



Description of key information ^



Normal Aharoni 8 A B I U



Additional information ^



Normal Aharoni 8 A B I U



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