

## Tabular formats for the safety expert report

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**Safety Expert Report – Format S1**

**Name of Company:**  
**Name of Product:**  
**Active Substancet(s):**

**PART 3A1: PRECISE IDENTIFICATION OF THE SUBSTANCE (ACTIVE)**

1.1	INN:	
1.2	IUPAC name:	
1.3	CAS number:	
1.4	Classification:	
1.5	Synonyms and abbreviations:	
1.6	Structural formula:	
1.7	Molecular formula:	
1.8	Molecular weight:	
1.9	Degree of impurity:	
1.10	Impurities:	
1.11	Physical properties:	
	Appearance:	
	Melting point:	
	Boiling point:	
	Vapour pressure:	
	pH:	
	Solubility in water:	
	Solubility in organic solvents:	
	Octanol water partition coefficient (Pow):	
	Density:	
	Refractive index:	
	Rotation:	

**Expert’s Comments on Active Substance (e.g. expected biological effects resulting from physical properties, relationship to similar compounds, whether well-established or novel, etc.)**

**For National Authority Use Only**

**Safety Expert Report – Format S2**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A1: PRECISE IDENTIFICATION OF THE SUBSTANCE (PRODUCT)**

Formulation:

Indications, including Dose Level and Route of Administration:

Flash Point/ Particle Size of Product/Spray Rate/etc. (as applicable):

**Expert's Comments on Formulation (e.g. nature of excipients, MRL status of excipients, flammability of formulation, likely routes of human exposure, frequency of use, quantities handled, etc.)**

**For National Authority Use Only**

**Safety Expert Report – Format S3**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A2: RELEVANT PHARMACOLOGICAL STUDIES**

2.1. Pharmacodynamics

Summary of Relevant Information

Effect	Location in Dossier
Desired therapeutic effects:	
Secondary pharmacological effects:	
Mode of action:	

**Expert's Comments on Relevance to Human Safety**

**For National Authority Use Only**

**Safety Expert Report – Format S4**

<b>Name of Company:</b>
<b>Name of Product:</b>
<b>Active Substance(s):</b>

**PART 3A2: RELEVANT PHARMACOLOGICAL STUDIES**

2.2. Pharmacokinetics in Laboratory Animals

The following pharmacokinetic studies have been carried out:

Species/Strain	Route	Dose Level/ Frequency	Hot or Cold	Absorption, Distribution, Metabolism or Excretion	Study No. or Literature Ref.

**Expert's Comments on Choice of Pharmacokinetic Studies (e.g. relevance of dosing schedule, route of administration, etc.)**

**For National Authority Use Only**

**Safety Expert Report – Format S5**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A2: RELEVANT PHARMACOLOGICAL STUDIES**

2.2. Pharmacokinetics in Laboratory Animals

Study Summary ñ Method	Study No.
------------------------	-----------

Study Identification:	Title:	GLP (Yes/No):
	Ref No:	Date:
	Location in Dossier:	
Test System:	Species:	Strain:
	Age:	Sex:
Test Substance:	Name:	Batch No:
	Dose Given (amount/frequency/duration):	Route of Admin:
	Radiolabel/Specific Activity	Vehicle:
Experimental Design:	Time Points:	No. Animals:
	Type and Timing of Sampling:	
Analytical Method:	Type of Method:	LOD and LOQ:
Treatment of Results:	Calculation of Pharmacokinetic Parameters (method/choice of parameters):	
Other Information:		

**For National Authority Use Only**

**Safety Expert Report – Format S6**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A2: RELEVANT PHARMACOLOGICAL STUDIES**

2.2. Pharmacokinetics in Laboratory Animals

Study Summary - Results (plasma) Study No:

Plasma Levels were (µg/l)

Animal No	Time Point 1	Time Point 2	Time Point 3	Time Point 4	Time Point 5	Time Point 6	Time Point 7	Time Point 8	Time Point 9	Time Point 10
1										
2										
3										
n										
Mean										
S.D.										

Animal No	Time Point 11	Time Point 12	Time Point 13	Time Point 14	Time Point 15	Time Point 16	Time Point 17	Time Point 18	Time Point 19	Time Point 20
1										
2										
3										
n										
Mean										
S.D.										

**Expert's Comments on Study (including details of pharmacokinetic parameters calculated)**

**For National Authority Use Only**

**Safety Expert Report – Format S7**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A2: RELEVANT PHARMACOLOGICAL STUDIES**

2.2. Pharmacokinetics in Laboratory Animals  
 Study Summary - Results (urine and faeces) Study No.

Concentrations in faeces were (µg/kg):

Animal No	Time Point 1	Time Point 2	Time Point 3	Time Point 4	Time Point 5	Time Point 6	Time Point 7	Time Point 8	Time Point 9	Time Point 10
1										
2										
3										
n										
Mean										
S.D.										

Concentrations in urine were (µg/l):

Animal No	Time Point 1	Time Point 2	Time Point 3	Time Point 4	Time Point 5	Time Point 6	Time Point 7	Time Point 8	Time Point 9	Time Point 10
1										
2										
3										
n										
Mean										
S.D.										

**Expert's Comments on Study (including details of pharmacokinetic parameters calculated)**

**For National Authority Use Only**

**Safety Expert Report – Format S8**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A2: RELEVANT PHARMACOLOGICAL STUDIES**

2.2 Pharmacokinetics in Laboratory Animals

Study Summary - Results (tissue distribution) Study No.

Concentrations in tissues were (µg/kg):

Animal No	Liver	Kidney	Skin	Fat	Muscle	Bile				
1										
2										
3										
n										
Mean										
S.D.										

Animal No										
1										
2										
3										
n										
Mean										
S.D.										

**Expert's Comments on Study (including details of pharmacokinetic parameters calculated)**

**For National Authority Use Only**

**Safety Expert Report – Format S9**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A2: RELEVANT PHARMACOLOGICAL STUDIES**

2.2 Pharmacokinetics in Laboratory Animals  
 Study Summary - Results (metabolism) Study No.

Metabolites found were:

Reference	Name

Each metabolite comprised the following percentage of total residue for the samples indicated at the times indicated:

Sample	Metabolite	Time Point 1	Time Point 2	Time Point 3	Time Point 4
Urine	A				
	B				
	C				
	N				
Liver	A				
	B				
	C				
	N				
Etc.					

**Proposed Metabolic Pathway (append if too large)**

**For National Authority Use Only**

**Safety Expert Report – Format S10**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A2: RELEVANT PHARMACOLOGICAL STUDIES**

2.2 Pharmacokinetics in Laboratory Animals

Expert's Conclusions on Pharmacokinetics

[Empty box for content]

**For National Authority Use Only**

[Empty box for content]

**Safety Expert Report – Format S11**

<b>Name of Company:</b>	
<b>Name of Product:</b>	
<b>Active Substance(s):</b>	

**PART 3A3: TOXICOLOGICAL STUDIES**

3.1 Single Dose Toxicity

The following single dose toxicity studies have been carried out:

Route	Species	Active Substance/Formulation	Study No. or Literature Ref.
Oral			
Dermal			
Inhalation			
Intravenous			
Intraperitoneal			

**Expert’s Comments on Choice of Studies (taking into consideration the routes of operator exposure, etc.)**

  
  
  
  
  
  
  
  
  
  

**For National Authority Use Only**

**Safety Expert Report – Format S12**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A3: TOXICOLOGICAL STUDIES**

## 3.1 Single Dose Toxicity

## Study Summary – Method

Study No.

Study Identification:	Title:	GLP (Yes/No):
	Ref No:	OECD Guideline:
	Location in Dossier:	Date:
Test System:	Species:	Strain:
	Age:	Sex:
Test Substance:	Name:	Batch No:
	Dose(s) Given:	Route of Admin:
	Observation Period:	Vehicle:
Experimental Design:	Type and Timing of Observations/Samples:	No. Animals/Dose:

**Results - deaths:**

Dose Group	_mg/kg bw		_mg/kg bw		_mg/kg bw		_mg/kg bw		_mg/kg bw		_mg/kg bw		_mg/kg bw	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F
0 - 6 h														
7 - 24 h														
2 - 7 d														
Total														

Adverse Effects, Including Reversibility

**Expert's Comments****For National Authority Use Only**

**Safety Expert Report – Format S13**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A3: TOXICOLOGICAL STUDIES**

3.1 Single Dose Toxicity

Expert's Conclusions on Single Dose Toxicity

[Empty box for expert's conclusions on single dose toxicity]

**For National Authority Use Only**



**Safety Expert Report – Format S15**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A3: TOXICOLOGICAL STUDIES**

3.2 Repeat Dose Toxicity  
 Study Summary - Method Study No.

Study Identification:	Title:	GLP (Yes/No):
	Ref No:	OECD Guideline:
	Location in Dossier:	Date:
Test System:	Species:	Strain:
	Age:	Sex:
Test Substance:	Name:	Batch No:
	Dose(s) Given:	Route of Admin:
	Duration of Study:	Vehicle:
Experimental Design:	Nature of Controls:	No. Animals/Dose:
	Type and Timing of Observations/Samples:	

**For National Authority Use Only**

<b>Safety Expert Report – Format S16</b>
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<b>Name of Company:</b> <b>Name of Product:</b> <b>ActiveSubstance(s):</b>
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<b>PART 3A3: TOXICOLOGICAL STUDIES</b>
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3.2 Repeat Dose Toxicity	
Study Summary - Results	Study No.

Food Consumption:
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Body Weight:
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Haematology:
--------------

Clinical Chemistry:
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Clinical Observations (including mortality):
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Organ Weights:
----------------

Histopathology:
-----------------

Ophthalmoscopy:
-----------------

Other:
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<b>For National Authority Use Only</b>
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**Safety Expert Report – Format S17**

**N**

**Name of Product:**

**Active Substance(s):**

**PART 3A3: TOXICOLOGICAL STUDIES**

3.2 Repeat Dose Toxicity

Expert' Conclusions on Repeat Dose Toxicity

**Optional Authority Use Only**

**Safety Expert Report – Format S18**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A3: TOXICOLOGICAL STUDIES**

3.3 Target Species Tolerance

The following target species tolerance studies have been carried out:

Route	Species	Duration	Dose Levels	Location of Summary Table (in Part IV)

Summary of Adverse Effects

**Expert’s Comments on Relevance of Studies to the Human Risk Assessment**

**For National Authority Use Only**

**Safety Expert Report – Format S19**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A3: TOXICOLOGICAL STUDIES**

3.4 Reproductive Toxicity

3.4.1 Effects on Reproduction

The following reproduction studies have been carried out:

Route	Species	Sex	Duration	Dose Levels	Study No. or Literature Ref.

**Expert's Comments on Choice of Studies**

**For National Authority Use Only**

**Safety Expert Report – Format S20**

<b>Name of Company:</b>	
<b>Name of Product:</b>	
<b>Active Substance(s):</b>	
<b>PART 3A3: TOXICOLOGICAL STUDIES</b>	
3.4 Reproductive Toxicity	
3.4.1 Effects on Reproduction	
Study Summary - Method	Study No.

Study Identification:	Title:	GLP (Yes/No):
	Ref No:	OECD Guideline:
	Location in Dossier:	Date:
Test System:	Species:	Strain:
	Age:	Sex:
Test Substance:	Name:	Batch No:
	Dose(s) Given:	Route of Admin:
	Duration of Dosing:	Vehicle:
Experimental Design:	Nature of Controls:	No. Animals/Dose:
	Type and Timing of Observations/Samples:	

<b>For National Authority Use Only</b>
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**Safety Expert Report – Format S21**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A3: TOXICOLOGICAL STUDIES**

3.4 Reproductive Toxicity

3.4.1 Effects on Reproduction

Study Summary - Results

Study No.

Food Consumption:

Body Weight of Adults:

Clinical Observations (including mortality):

Weight of Litter:

Number of off-spring (live and dead):

Sex of off-spring:

Gross Pathology of Adults:

Gross Pathology of off-spring:

Histopathology of Adults:

Other:

**For National Authority Use Only**



**Safety Expert Report – Format S23**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A3: TOXICOLOGICAL STUDIES**

3.4. Reproductive Toxicity

3.4.2. Embryotoxicity/Foetotoxicity including Teratogenicity

The following embryotoxicity/foetotoxicity studies have been carried out:

Route	Species	Sex	Duration	Dose Levels	Study No. or Literature Ref.

**Expert's Comments on Choice of Studies**

**For National Authority Use Only**

**Safety Expert Report – Format S24**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

3.4 Reproductive Toxicity  
 3.4.2. Embryotoxicity/Foetotoxicity including Teratogenicity  
 Study Summary - Method Study No.

Study Identification:	Title:	GLP (Yes/No):
	Ref No:	OECD Guideline:
	Location in Dossier:	Date:
Test System:	Species:	Strain:
	Age:	Sex:
Test Substance:	Name:	Batch No:
	Dose(s) Given:	Route of Admin:
	Duration of Dosing:	Vehicle:
Experimental Design:	Nature of Controls:	No. Animals/Dose:
	Type and Timing of Observations/Samples:	

**For National Authority Use Only**

**Safety Expert Report – Format S25**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

3.4. Reproductive Toxicity

3.4.2. Embryotoxicity/Foetotoxicity including Teratogenicity

Study Summary - Results

Study No.

Food Consumption:

Body Weight:

Clinical Observations (including mortality):

Gross Pathology (with emphasis on reproductive system):

Weight of Foetuses:

Sex of Foetuses:

Gross Appearance of Foetuses:

Visceral Effects:

Skeletal Effects:

Other:

**For National Authority Use Only**

**Safety Expert Report – Format S26**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A3: TOXICOLOGICAL STUDIES**

3.4 Reproductive Toxicity

3.4.2. Embryotoxicity/Foetotoxicity including Teratogenicity

Expert's Conclusions on Embryotoxicity/Foetotoxicity

[Empty box for expert's conclusions on embryotoxicity/foetotoxicity]

**For National Authority Use Only**

[Empty box for national authority use only]

**Safety Expert Report – Format S27**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A3: TOXICOLOGICAL STUDIES**

3.5 Mutagenicity

The following mutagenicity studies have been carried out:

Type of Study	Study No. or Literature Ref.
Gene mutations in bacterial cells	
Chromosome aberrations in mammalian cells ( <i>in vitro</i> )	
Gene mutations in eukaryotic cells	

**Expert's Comments on Choice of Studies:**

**For National Authority Use Only**

**Safety Expert Report – Format S28**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A3: TOXICOLOGICAL STUDIES**

3.5 Mutagenicity  
 Study Summary

Study Identification:	Title:	GLP (Yes/No):
	Ref No:	OECD Guideline:
	Location in Dossier:	Date:
Test System:	Species/Cell Type:	Strain:
Test Substance:	Name:	Batch No:
	Concentration(s) Used:	Vehicle:
Experimental Design:	Control Substance (no metabolic activation):	Duration of Exposure:
	Control Substance (with metabolic activation):	

Summary of Results:

**Expert's Comments and Conclusion Regarding Study**

**For National Authority Use Only**

**Safety Expert Report – Format S29**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A3: TOXICOLOGICAL STUDIES**

3.5 Mutagenicity

Expert's Conclusions on Mutagenicity

[Empty box for Expert's Conclusions on Mutagenicity]

**For National Authority Use Only**

[Empty box for National Authority Use Only]

**Safety Expert Report – Format S30**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A3: TOXICOLOGICAL STUDIES**

3.6 Carcinogenicity

The following carcinogenicity studies have been carried out:

Route	Species	Duration	Dose Levels	Study No. or Literature Ref.

**Expert's Comments on Choice of Studies or Justification for Absence of Studies**

**For National Authority Use Only**

**Safety Expert Report – Format S31**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A3: TOXICOLOGICAL STUDIES**

3.6 Carcinogenicity

Study Summary - Method

Study Identification:	Title:	GLP (Yes/No):
	Ref No:	OECD Guideline:
	Location in Dossier:	Date:
Test System:	Species:	Strain:
	Age:	Sex:
Test Substance:	Name:	Batch No:
	Dose(s) Given:	Route of Admin:
	Duration of Study:	Vehicle:
Experimental Design:	Nature of Controls:	No. Animals/Dose:
	Type and Timing of Observations/Samples:	

**For National Authority Use Only**

**Safety Expert Report – Format S32**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A3: TOXICOLOGICAL STUDIES**

3.6 Carcinogenicity  
Study Summary - Results

Food Consumption:

Body Weight:

Haematology:

Clinical Observations (including mortality):

Organ Weights:

Gross Pathology:

Histopathology:

Summary of Tumour Incidence:

Expert's Interpretation of Findings:

**For National Authority Use Only**

**Safety Expert Report – Format S33**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A3: TOXICOLOGICAL STUDIES**

3.6 Carcinogenicity

Expert's Conclusions on Carcinogenicity

[Empty box for expert's conclusions on carcinogenicity]

**For National Authority Use Only**

[Empty box for national authority use only]

**Safety Expert Report – Format S34**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A4: STUDIES OF OTHER EFFECTS**

4.1 Special Studies including specific target organ toxicity (eg immunotoxicity, endocrine function tests, liver and renal function tests, effects on enzymes, neurotoxicity, sensitisation, skin and eye irritation, inhalation toxicity, mechanistic studies, relay toxicity studies, etc. as appropriate)

The following special studies have been carried out:

**Expert’s Comments on Relevance of Special Studies or Omission of Studies Needed**

**For National Authority Use Only**

**Safety Expert Report – Format S35**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A4: STUDIES OF OTHER EFFECTS**

4.2 Microbiological Studies (for compounds with antimicrobial activity)

The following studies have been carried out:

**Expert's Comments on Choice of Studies**

**For National Authority Use Only**

**Safety Expert Report – Format S36**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A4: STUDIES OF OTHER EFFECTS**

4.3 Observations in Humans

Summary of Information Available

Dosage (amount, frequency, route, reason)	Observations	Reference/Location in Dossier

**Expert's Comments on Relevance of Observations in Humans**

**For National Authority Use Only**

**Safety Expert Report – Format S37**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**PART 3A4: STUDIES OF OTHER EFFECTS**

**4.4 Studies on Metabolites and Other Substances**

The following studies have been carried out:

**Expert's Comments on Choice of Studies**

**For National Authority Use Only**

**Safety Expert Report – Format S38**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**EXPERT'S CONCLUSIONS ON SAFETY**

**User Safety** (Adverse Effects, Exposure, Risk Assessment and Risk Management)

[Empty box for expert's conclusions on safety]

**For National Authority Use Only**

[Empty box for national authority use only]

**Safety Expert Report – Format S39**

**Name of Company:**  
**Name of Product:**  
**Active Substance(s):**

**EXPERT'S CONCLUSIONS ON SAFETY**

**Consumer Safety** (Summary of NOELs and Derivation of ADI)

**For National Authority Use Only**