

NEW SOURCE PROFORMA

APPLICATION TO BECOME A RECOGNISED SOURCE OF AN ACTIVE
SUBSTANCE USED IN NON- AGRICULTURAL PESTICIDES UNDER THE
CONTROL OF PESTICIDES REGULATIONS 1986 (COPR)

**Please complete the pro forma and attach relevant raw data. Please read the
guidance notes on inside pages before filling in the relevant sections on
facing pages.**

If necessary please use supplementary sheets.

BEFORE COMPLETING THIS PROFORMA YOU SHOULD READ THE
GUIDANCE DOCUMENT ENTITLED "NEW SOURCE GUIDANCE" WHICH IS
AVAILABLE AT <http://www.hse.gov.uk/biocides/>

Guidance on identity of the active substance

1.1.1	Common name:	Where available the commonly used International Organisation for Standardisation (ISO) name or alternatively the British Standard Institute (BSI) name should be provided or, if not yet established, the proposed name.
1.1.2	IUPAC name:	Systematic chemical nomenclature according to the International Union of Pure and Applied Chemistry.
1.1.3	Other synonyms or codes:	Development codes, company codes, any name by which the active ingredient is also known, including trade names.
1.1.4	CAS Number:	The Chemical Abstracts Service number. Each number is unique to one chemical. If not allocated then please state "not yet allocated".
1.1.5	EINECS/ELINCS No:	For substances 'on the market' prior to 1981 an EINECS number should be quoted. For 'new' substances (i.e. those notified after 1981) an ELINCS number should be quoted.
1.1.6	Structural formula:	Structures should be drawn to show 3-dimensional aspects where possible, for example, in the case of stereoisomers. Bond lengths need not be exact in order to place the structure within the space provided.
1.1.7	Site of manufacture:	Company name and manufacturing site address.

1.1 IDENTITY OF THE ACTIVE SUBSTANCE

1.1.1	BSI name:	
1.1.2	IUPAC name:	
1.1.3	Other synonyms or codes:	
1.1.4	CAS Number:	
1.1.5	EINECS/ELINCS No:	
1.1.6	Structural formula:	
1.1.7	Site of manufacture:	

Guidance on analysis of technical active ingredient

1.2.1 Percentage purity of technical active substance:

This section should be completed using the certified manufacturing limits ensuring that the five batch analysis demonstrates that they are achievable.

Typical Batch purity:	The mean value of the 5-batch analysis should be reported.
Minimum purity:	The minimum value from the technical specification i.e. certified manufacturing limit.
Range:	This should encompass the minimum and maximum values from the technical specification i.e. the certified manufacturing limits.
Where appropriate % of individual isomers:	Isomer ratios should be quoted where appropriate e.g 80:20 (cis:trans)
Comments:	Any relevant comments.

1.2.2 Impurities in technical active substance:

Impurity	Max %w/w	CAS no.
1	Impurities should be identified by IUPAC name and synonyms where appropriate.	Certified maximum values correct to 2 significant figures.
2		See 1.1.4
3		
4		
5		
6		
Comments:	Any relevant comments.	

1.2.3 Additives in technical active substance:

Name, function and certified maximum amount (% or ppm) of any stabilising agent, inhibitor or other additive.

Additives	Max %w/w	CAS No.
1	Any additives in the technical material should be identified by IUPAC name and synonyms where appropriate.	Certified maximum values correct to 2 significant figures.
2		See 1.1.4
3		
Comments:	Any relevant comments.	

1.3 ANALYSIS OF TECHNICAL ACTIVE INGREDIENT

1.2.1 Percentage purity of technical active substance:

Typical Batch purity:		% w/w			
Minimum purity:		% w/w			
Range:	Min		- Max		% w/w
Where appropriate % of individual isomers:					
Comments:					

1.2.2 Impurities in technical active substance:

Impurity	Max %w/w	CAS no.
1		
2		
3		
4		
5		
6		
7		
Comments:		

1.2.3 Additives in technical active substance:

Additive	Max %w/w	CAS No.
1		
2		
3		
Comments:		

Guidance on five-batch analysis

Component		Batch Numbers				
		Batch numbers of each of the 5 batches should be reported				
Component		% w/w of component				
Active substance (total):		Reported value of active ingredient content should be reported.				
Isomers:		Where applicable the content of each single isomer should be reported.				
Impurities:						
1		Values for each impurity should be reported correct to 2 significant figures.				
2						
3						
4						
5						
Additives:						
1		Where applicable any additives to the technical active ingredient should be reported correct to 2 significant figures				
2						
Accountability:		The sum of active ingredient, impurities and additives should be reported.				
Comments:		Any relevant comments.				

1.3 FIVE-BATCH ANALYSIS

Component	Batch Numbers				
	% w/w of component				
Active substance (total):					
Isomers:					
Impurities:					
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
Additives:					
1					
2					
Accountability:					
Comments:					

Guidance on methods of analysis

Details of analytical methods used to obtain the batch analysis results must be reported.

Validation data for the methods of analysis must be included. Please refer to the “Guidelines for validation of analytical methods for non-agricultural pesticide active ingredients and their respective products” for validation requirements.

Raw data generated from the batch analysis must be provided.

1.4 Analytical method for the determination of active/impurities/additives in technical material:

Analytical method:	e.g. HPLC, LC, GC-MS
Sample preparation:	e.g. Weigh exactly 25 mg of technical sample into a 50 ml volumetric flask and add dichloromethane to dissolve.
Standard preparation: (inc. calibration)	e.g. Internal standard was prepared by addition of 1,4-dibromonaphthalene to acetonitrile. Standard solutions were prepared by addition of external standard to internal standard solution and made up to mark with acetonitrile.
Column:	e.g. ODS-5, 25 mm x 4.6 mm (internal diameter) x 5 microns (film thickness)
Eluent:	e.g. Acetonitrile:water (80:20)
Temperature:	e.g. 50°C to 250°C at 10°C min ⁻¹ for 5 minutes
Detector:	e.g. UV at 254 nm
Retention time(s):	Retention time for each analysed component should be reported for chromatographic methods.
Validation:	
Accuracy:	Mean recovery encompassing a range 20% below the lowest expected and 20% above the highest expected concentration.
Repeatability:	Mean, % RSD and number of determinations should be reported.
Reproducibility:	Mean, % RSD and number of determinations should be reported.
Specificity:	
LOD:	Limit of detection
LOQ:	Limit of quantitation
Linearity:	Coefficient of correlation
Range:	Upper and lower concentration levels that have been demonstrated to be determined with precision, accuracy and linearity using the method as written.
Robustness:	
Comments:	Any relevant comments.

Reference:	Study report reference
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1.4.1 Analytical method for the determination of the active substance in technical material:

Analytical method:	
Sample preparation:	
Standard preparation: (inc. calibration)	
Column:	
Eluent:	
Temperature:	
Detector:	
Retention time(s):	
Validation:	
Accuracy:	
Repeatability:	
Reproducibility:	
Specificity:	
LOD:	
LOQ:	
Linearity:	
Range:	
Robustness:	
Comments:	
Reference:	

1.4.2 Analytical method for the determination of individual isomers in technical material:

Analytical method:	
Sample preparation:	
Standard preparation: (inc. calibration)	
Column:	
Eluent:	
Temperature:	
Detector:	
Retention time(s):	
Validation:	
Accuracy:	
Repeatability:	
Reproducibility:	
Specificity:	
LOD:	
LOQ:	
Linearity:	
Range:	
Robustness:	
Comments:	
Reference:	

1.4.3 Analytical method for the determination of impurities in technical material:

Analytical method:	
Sample preparation:	
Standard preparation: (inc. calibration)	
Column:	
Eluent:	
Temperature:	
Detector:	
Retention time(s):	
Validation:	
Accuracy:	
Repeatability:	
Reproducibility:	
Specificity:	
LOD:	
LOQ:	
Linearity:	
Range:	
Robustness:	
Comments:	
Reference:	

1.4.4 Analytical method for the determination of additives in technical material:

Analytical method:	
Sample preparation:	
Standard preparation: (inc. calibration)	
Column:	
Eluent:	
Temperature:	
Detector:	
Retention time(s):	
Validation:	
Accuracy:	
Repeatability:	
Reproducibility:	
Specificity:	
LOD:	
LOQ:	
Linearity:	
Range:	
Robustness:	
Comments:	
Reference:	