

Draft Assessment Report

Evaluation of Active Substances

Plant Protection Products

Prepared according to **Regulation (EC) 1107/2009**
as it applies in Great Britain

Elemental iron

Volume 3 – B.2 (PPP) – Final Bite

Great Britain

January 2024

Version History

When	What
November 2021	Initial DAR
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B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT ‘FINAL BITE’

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1. APPEARANCE						
Physical state and colour B.2.1/01	Visual inspection and comparison to other characteristic odours	‘Final Bite’ 1% elemental iron powder Batch: KM8017420OH	Blue granular solid with a synthetic odour	Acceptable	Y	2018 Study No.: Mo5845
B.2.2. EXPLOSIVE AND OXIDIZING PROPERTIES						
Explosive properties B.2.2/01	Reasoned case	-	From the active substance data for elemental iron, the active substance is not classified for explosive properties. Inspection of the identity of the co-formulants in ‘Final Bite’ and their respective MSDSs indicates that none of the co-formulants are classified for explosive properties either. Therefore, it is considered that the overall formulated product is not classified as explosive.	Acceptable	-	-
Oxidizing properties B.2.2/02	Reasoned case	-	From the active substance data for elemental iron, the active substance is not classified for oxidising properties. Inspection of the identity of the co-formulants in ‘Final Bite’ and their respective MSDSs indicates that none of the co-formulants are classified for oxidising properties either. Therefore,	Acceptable	-	-

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			it is considered that the overall formulated product is not classified as oxidising.			
B.2.3. FLAMMABILITY AND AUTO-FLAMMABILITY						
Flash point of the liquids formulations B.2.3/01			Not required of an RB formulation.			
Flammability of solid formulations B.2.3/02	A.10	'Final Bite' 1% elemental iron powder Batch: KM8017420OH	Test item could not be ignited with a flame in the preliminary 120s test, so the test item is not considered to be flammable.	Correct method used. Acceptable	Y	██████████ 2018 Study No.: Mo5845
Self-heating of formulation B.2.3/03	A. 16	'Final Bite' 1% elemental iron powder Batch: KM8017420OH	No self-ignition temperature was observed up to the maximum test temperature of 416°C.	Correct method used. Acceptable.	Y	██████████ 2017 Report no.: PS20170428-1
B.2.4. ACIDITY/ALKALINITY AND PH VALUE						
pH of the neat aqueous formulation B.2.4/01						
pH of a 1 % dilution of the solid or non aqueous formulation B.2.4/02	CIPAC MT 75.3	'Final Bite' 1% elemental iron powder Batch: KM8017420OH	1% w/v dispersion in deionised water at 22.4°C; pH 4.5	Correct method used. Acidity and alkalinity not tested as $10 < \text{pH} > 4$. Acceptable	Y	██████████ 2018 Study No.: Mo5845
Acidity / Alkalinity B.2.4/03			Not required as $10 < \text{pH} > 4$.			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.5. VISCOSITY AND SURFACE TENSION						
Viscosity of the liquid formulation B.2.5/01			Not required of an RB formulation.			
Surface tension of the formulation B.2.5/02			Not required of an RB formulation.			
B.2.6. RELATIVE DENSITY AND BULK DENSITY						
Relative density of the liquid formulation B.2.6/01			Not required of an RB formulation.			
Bulk density (pour and tap) of powder or granules B.2.6/02	CIPAC MT 186	'Final Bite' 1% elemental iron powder Batch: KM80174200H	Pour density = 0.7668 g/cm ³ Tap density = 0.7806 g/cm ³	Correct method used. Acceptable	Y	██████████ 2018 Study No.: Mo5845 ██████████ 2019 Amendment No.1 to Study No.: Mo5845
B.2.7. STORAGE STABILITY AND SHELF-LIFE: EFFECTS OF TEMPERATURE ON TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT						
Stability after accelerated storage (54°C during 14 days, 8 weeks at 40°C, 12 weeks at 35°C or 18 weeks at 30°C) B.2.7/01		'Final Bite' 1% elemental iron powder Batch: KM80174200H	Test results after 2 weeks at 45°C; test items stored in sealed PET/PET bags Appearance Initial: Blue, granular solid	Appearance	Y	██████████ 2018a Study No.: Mo6000

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			<p>After storage: Blue granular solid. No microbial growth was seen.</p> <p>Odour Initial: Weak synthetic odour After storage: Weak synthetic odour.</p> <p>Packaging Initial: Container in good condition, dealed without leakage, no ballooning or change of panelling observed. After storage: Container in good condition, sealed without leakage, no ballooning or change of panelling observed.</p> <p>Weight of packaging after storage -1.2% (n=4; range = 1.14-1.26%)</p> <p>Active substance content Active substance content was determined in duplicate for 2 samples before after storage. Initial: Sample 18-09724/1a = 1.09% Fe Sample 18-09724/1b = 1.10% Fe</p>	<p>No change in appearance after storage. Acceptable.</p> <p>Odour No change in odour after storage. Acceptable.</p> <p>Packaging No change in packaging appearance after storage. Acceptable.</p> <p>Weight of packaging after storage Not a significant change in packaging weight after storage. Acceptable.</p> <p>Active substance content No change in active content after storage. Active substance content within tolerance limit of decalred content. Acceptable.</p>		<p><i>Active substance content</i> 2018 Final report 18-09724-2</p>

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			<p><u>Mean = 1.11% Fe</u></p> <p>After 2 week accelerated storage: Sample 18-09724/2a = 1.09% Fe Sample 18-09724/2b = 1.11% Fe <u>Mean = 1.11% Fe</u></p> <p>Active content determined using method as described in validation report Validation Report 42MV18001/E1 (R-39460).</p> <p>Relevant impurities content All of the relevant impurities in elemental iron technical material are non-volatile elements, the levels of which are fixed at the point of manufacture. The levels cannot change during storage of the formulation and therefore this data is not required.</p> <p>Batch 2290598 of elemental iron was used to formulate batch KM8017420OH of Final Bite, which was used in the physical-chemical properties tests. Batch 2290598 of elemental iron was assessed as part of the 5-batch analysis study, which</p>	<p>Method described in Validation Report 42MV18001/E1 is fully validated in accordance with SANCO 3030/99/4 ; full condieration is reported in Part B5.</p> <p>Relevant impurities content Acceptable.</p>		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			confirms that the technical material complies with the specification.			
		CIPAC MT 75.3	<p>pH; 1% dispersion in deionised water</p> <p>Initial: pH 4.5 (n=2; measured at 20.95°C)</p> <p>After storage: pH 4.2 (n=2; measured at 20.25°C)</p>	<p>pH</p> <p>Correct method used. 0.3 change in pH; not a significant change after storage. Acceptable.</p>		
		CIPAC MT 186	<p>Bulk density (initial data only)</p> <p>Pour density = 0.786g/mL</p> <p>Tap density = 0.800g/mL</p> <p>Attrition resistance</p> <p>Initial: 99.94% (n=2)</p> <p>After storage: 99.8% (n=2)</p>	<p>Bulk density</p> <p>Correct method used. Acceptable.</p>		
		CIPAC MT 178	<p>Attrition resistance</p> <p>Initial: 99.94% (n=2)</p> <p>After storage: 99.8% (n=2)</p>	<p>Attrition resistance</p> <p>Correct method used. No significant change after storage. Determination of particle size not required. Acceptable.</p>		
		CIPAC 171.1	<p>Dust content</p> <p>Initial: Optical dust factor = 0.81, therefore nearly dust free</p> <p>After storage: Optical dust factor = 1.51, therefore nearly dust free</p> <p>Flowability</p> <p>Initial: Test item spontaneously passed through a 5mm sieve,</p>	<p>Dust content</p> <p>Correct method used, and interpretation correct for both initial and after storage tests. Dust content does increase (nearly doubles) after storage, however interpretation remains the same, therefore acceptable.</p>		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference																	
		CIPAC 172	After storage: Test item sponatneously passed through a 5mm sieve.	Flowability Correct method used. No change after storage. Acceptable.																			
		CIPAC MT 170	Particle size distribution Intial:	Particle size distribution Correct method used. Initial results show over 99% of sample was found on a 250µm sieve indicating no more than 1% of sample would be found on a 50µm sieve. After storage, results similarly show over 100% of sample was found on a 250µm sieve indicating no more than 1% of sample would be found on a 50µm sieve. No inhalation study required. No significant change in particle size distribution observed after storage, therefore acceptable.																			
			<table><tr><td>Sieve (µm)</td><td>Sum of residue on sieves (%)</td></tr><tr><td>250</td><td>99.81</td></tr><tr><td>500</td><td>99.81</td></tr><tr><td>1000</td><td>99.81</td></tr><tr><td>2000</td><td>99.81</td></tr><tr><td>2500</td><td>76.91</td></tr><tr><td>3350</td><td>00.00</td></tr><tr><td>5000</td><td>00.00</td></tr></table>				Sieve (µm)	Sum of residue on sieves (%)	250	99.81	500	99.81	1000	99.81	2000	99.81	2500	76.91	3350	00.00	5000	00.00	
			Sieve (µm)				Sum of residue on sieves (%)																
			250				99.81																
			500				99.81																
			1000				99.81																
			2000				99.81																
			2500				76.91																
			3350				00.00																
			5000				00.00																
			After storage:																				
			<table><tr><td>Sieve (µm)</td><td>Sum of residue on sieves (%)</td></tr><tr><td>250</td><td>100.21</td></tr><tr><td>500</td><td>100.21</td></tr><tr><td>1000</td><td>100.21</td></tr><tr><td>2000</td><td>100.04</td></tr><tr><td>2500</td><td>68.78</td></tr><tr><td>3350</td><td>00.00</td></tr><tr><td>5000</td><td>00.00</td></tr></table>				Sieve (µm)	Sum of residue on sieves (%)	250	100.21	500	100.21	1000	100.21	2000	100.04	2500	68.78	3350	00.00	5000	00.00	
			Sieve (µm)				Sum of residue on sieves (%)																
			250				100.21																
			500				100.21																
			1000				100.21																
			2000				100.04																
			2500				68.78																
		3350	00.00																				
5000	00.00																						

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			No significant changes were observed in the technical characteristics of the formulation after accelerated storage in the commercial packaging for 2 weeks at 54°C.			
Effect of low temperature on stability of liquid formulation B.2.7/02			Not required as the formulation is a solid			
Shelf life following storage at ambient temperature B.2.7/03			Study is ongoing; data not available.			
B.2.8. TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT						
B.2.8.1. Wettability						
Wettability of solid formulation B.2.8.1/01			Not required of an RB formulation.			
B.2.8.2. Persistence foaming						
Persistence of foaming of the diluted formulation B.2.8.2/01			Not required of an RB formulation.			
B.2.8.3. Suspensibility						
Suspensibility of water dispersible formulation			Not required of an RB formulation.			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference																		
B.2.8.3/01																								
Spontaneity of dispersion of water dispersible formulation B.2.8.3/02			Not required of an RB formulation.																					
Dispersion stability of SE, OD or EG formulation B.2.8.3/03			Not required of an RB formulation.																					
B.2.8.4. Degree of dissolution and dilution stability																								
Degree of dissolution of water soluble formulation B.2.8.4/01			Not required of an RB formulation.																					
Dilution stability of water soluble formulation B.2.8.4/02			Not required of an RB formulation.																					
B.2.8.5. Particle size distribution, dust content, attrition and mechanical stability																								
B.2.8.5.1. Particle size distribution																								
Wet sieve test of water dispersible formulation B.2.8.5.1/01			Not required of an RB formulation.																					
Size distribution of particles of powder or suspension concentrate formulation B.2.8.5.1/02	CIPAC MT 170	‘Final Bite’ 1% elemental iron powder Batch: KM8017420OH	<div>Dry sieve test:<table><tr><th>Sieve size (µm)</th><th>Residue on sieve (g)</th><th>Sum of residues (%)</th></tr><tr><td>75</td><td>0.00</td><td>0</td></tr><tr><td>125</td><td>0.00</td><td>0</td></tr><tr><td>250</td><td>0.00</td><td>0</td></tr><tr><td>500</td><td>0.00</td><td>0</td></tr><tr><td>1000</td><td>0.01</td><td>0.01</td></tr></table></div>	Sieve size (µm)	Residue on sieve (g)	Sum of residues (%)	75	0.00	0	125	0.00	0	250	0.00	0	500	0.00	0	1000	0.01	0.01	Correct method used. No residue found on 75µm, therefore no inhalation study required. Acceptable.	Y	<div></div> 2018 Study No.: Mo5845
Sieve size (µm)	Residue on sieve (g)	Sum of residues (%)																						
75	0.00	0																						
125	0.00	0																						
250	0.00	0																						
500	0.00	0																						
1000	0.01	0.01																						

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
			2000	93.64	99.99			
Nominal size range of granule B.2.8.5.1/03			Not required of an RB formulation.					
B.2.8.5.2. Dust content								
Dust content of granular formulation B.2.8.5.2/01	CIPAC MT 171		Dust content: Optical dust factor = 1.33, test item is classified as nearly dust-free.			Correct method used. Acceptable.	Y	<div></div> 2018 Study No.: Mo5845
B.2.8.5.3. Attrition								
Attrition characteristics of granules and tablets B.2.8.5.3/01	CIPAC MT 178	‘Final Bite’ 1% elemental iron powder Batch: KM8017420OH	Attrition resistance: 100%			Correct method used. Attrition resistance greater than 98%, therefore no evidence is required to show the material can be applied through application equipment. Acceptable.	Y	<div></div> 2018 Study No.: Mo5845
B.2.8.5.4. Hardness and integrity								
Hardness of tablets B.2.8.5.4/01			Not required of an RB formulation.					
Integrity of tablets B.2.8.5.4/02			Not required of an RB formulation.					
B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability								
Emulsifiability, emulsion stability and re-emulsifiability of formulation B.2.8.6/01			Not required of an RB formulation.					
B.2.8.7. Flowability, pourability and dustability								

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Flowability of granular formulation B.2.8.7/01	CIPAC MT 172+170	'Final Bite' 1% elemental iron powder Batch: KM80174200H	No residue remaining on a 5mm sieve after tapping, therefore indicating that no caking had occurred.	Acceptable.	Y	2018 Study No.: Mo5845
Pourability of suspensions B.2.8.7/02			Not required of an RB formulation.			
Dustability of dustable powders after accelerated storage B.2.8.7/03			Not required of an RB formulation.			
B.2.9. PHYSICAL AND CHEMICAL COMPATIBILITY WITH OTHER PRODUCTS INCLUDING PLANT PROTECTION PRODUCTS WITH WHICH ITS USE IS TO BE AUTHORISED						
Physical and chemical compatibility of tank mixtures B.2.9/01			'Final Bite' is not intended to be co-applied in a mixture with other plant protection products, therefore no physical or chemical compatibility data are required.	Acceptable.		
B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS						
Distribution and adhesion to seeds B.2.9.10/01			Not required of an RB formulation.			
B.2.11. OTHER STUDIES						
			No other studies were conducted.	Noted.		

'Final Bite' is a nearly dust-free Ready to use Bait (RB) formulation, containing 1% of Elemental Iron. It is a blue granular solid, with a synthetic odour. The formulation is not explosive, oxidising or flammable, and therefore no classification is required for the product. A 1% solution of 'Final Bite' has a pH of between 4.2 and 4.5. Its pour and tap density are 0.7668 g/cm³ and 0.7806 g/cm³ respectively. On completing a dry sieve test, no inhalation study was required and the formulation has 100% attrition resistance.

The physical and chemical properties of this product indicate that the product fulfils the requirements of a ready to use bait formulation type. The product is not intended to be co-applied in a mixture with other plant protection products, therefore no physical or chemical compatibility data are required. This is acceptable from a chemistry perspective.

It is noted that issues with the pellet integrity upon application using commercial application equipment was noted in the efficacy section (see DAR Vol 3 CP B3, section B.3.5.). The recommended application equipment stated on the product label was adjusted accordingly.

The formulation demonstrated acceptable physical and chemical properties after accelerated storage at 54 ± 2°C for two weeks in PET/PET bags.

Data must be provided showing satisfactory chemical and physical properties for the product and their retention after ambient storage for two years in the commercial packaging.

B.2.12. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
B.2.1/01 B.2.3/02 B.2.4/02 B.2.6/02 B.2.8.5.1/02 B.2.8.5.2/01 B.2.8.5.3/01 B.2.8.7/01	██████	2018	Determination of physico-chemical Properties for Final Bite BioGenius GmbH Analytics Report No. Mo5845 ADAMA Makhteshim Ltd. GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies.	ADAMA Makhteshim Ltd	None
B.2.3/03	██████	2017	Autoflammability (solids-determination of relative self-ignition temperature) A.16. BioGenius GmbH Analytics Report No. PS20170428-1 GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies.	ADAMA Makhteshim Ltd	None
B.2.6/02	██████	2019	Determination of physico-chemical Properties for Final Bite; Amendment No. 1 to Final Report BioGenius GmbH Analytics Report No. Mo5845 ADAMA Makhteshim Ltd. GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies.	ADAMA Makhteshim Ltd	None
B.2.7	██████	2018a	Determination of physico-chemical properties and Storage Stability Tests for Final Bite: 2 weeks at 54°C, 8 weeks at 40°C and up to 24 months at 20°C BioGenius GmbH Analytics Report No. Mo6000 ADAMA Makhteshim Ltd. GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies.	ADAMA Makhteshim Ltd	None
B.2.7	██████	2018	Determination of Iron in the Test Item Final Bite using XRF-Spectroscopy Henkel AG&Co. KGaA Report No. Mo6000 ADAMA Makhteshim Ltd. GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies.	ADAMA Makhteshim Ltd	None