This is a draft document and contains references to EU legislation and Commission Communications. For the appropriate GB legislation please refer the HSE website at www.hse.gov.uk/pesticides/index.htm. Whilst these legislative references have changed this does not result in any substantive changes to the technical guidance outlined.

Final Draft

GUIDANCE DOCUMENT FOR THE GENERATION AND EVALUATION OF DATA ON THE PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF PLANT PROTECTION PRODUCTS UNDER REGULATION (EC) No. 1107/2009 OF THE EU PARLIAMENT AND COUNCIL ON PLACING PLANT PROTECTION PRODUCTS ON THE MARKET

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INTRODUCTION

The intention of this guidance document is to describe the physical, chemical and technical data required to support the registration/authorisation of a formulation. These notes are intended to provide guidance on the scientific data requirements for plant protection products as they are set out in Regulation (EU) No. 284/2013 in accordance with Regulation (EC) 1107/2009 concerning the placement of Plant Protection Products (PPPs) on the market.

This document covers the principal preparation types currently used. Where a preparation type has not been included in the guidance, then applicants are encouraged to discuss this with the appropriate Member State Regulatory Authority at the earliest opportunity.

In considering the chemical, physical and technical characteristics and shelf-life requirements for a plant protection product, the aim should be to show the PPP may be safely and efficaciously applied according to label instructions, and that the preparation retains the active substance and physical/chemical/technical characteristics on storage.

These guidelines are intended to cover the data requirements for chemical pesticides. Whilst they are not intended for biological pesticides, some of the requirements may in principle remain valid. Biological pesticides will be considered on a case by case basis, but as with the case of chemical pesticides, the basis of the data required will be to show the preparation can be safely and efficaciously applied.

In general, guidance is provided by Annex point in accordance with Commission communication in the framework of the implementation of Commission Regulation (EU) No 284/2013 (2013/C 95/02). Where an Annex point is self-explanatory no guidance is provided.

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1 IDENTITY OF THE PLANT PROTECTION PRODUCT

1.1 Applicant

The name and address of the applicant shall be provided, as well as the name, position, telephone, e-mail address and telefax number of a contact point.

1.2 Producer of the plant protection product and the active substance(s)

The name and address of the producer of the plant protection product and of each active substance in the plant protection product shall be provided, as well as the name and address of each manufacturing plant in which the plant protection product and active substance are manufactured. A contact point (name, telephone, e-mail address and telefax number) shall be provided.

If the active substance originates from a producer from which data in accordance with Regulation (EU) No 283/2013 have not been submitted previously, data to address those requirements shall be provided in order to establish equivalence of the active substance.

1.3 Trade name or proposed trade name and producer's development code number of the preparation if appropriate

All former and current trade names and proposed trade names and development code numbers of the plant protection product shall be provided. Where trade names and code numbers referred to, relate to similar but different plant protection products, full details of the differences shall be provided. The proposed trade name shall be such that it does not give rise to confusion with the trade name of already authorised plant protection products. Each code number shall be specific to a unique plant protection product.

1.4 Detailed quantitative and qualitative information on the composition of the plant protection product

1.4.1 Composition of the plant protection product

Full details of the composition of the plant protection product must be submitted with each application. This includes the content of the active substance(s), safeners, synergists and other co-formulants (for which compositional details should be provided).

The declared (nominal) active substance(s) content should be stated with tolerance limits. The content should be declared in terms of pure active substance in accordance with the identity established in the implementing regulation. This nominal target should also be the declared label content. In addition, the content of the technical active substance(s) (based on the specified minimum purity for that source) and, where relevant, the corresponding content of the variant (e.g. salts and esters) of the active substance(s) should be given.

e.g. 'x g/L or g/kg of the salt/ester which is equivalent to y g/L or g/kg of the free acid.'

For hydrated salts such as ferrous sulfate the active substance content must be declared in terms of the amount of hydrated salt present with a statement declaring the amount of the anhydrous form present.

e.g. x g/kg of ferrous sulfate heptahydrate equivalent to y g/kg anhydrous ferrous sulfate.

In the case of encapsulated formulations (e.g. capsule suspension, CS), in addition to the content of the active substance (total content), the free (non-encapsulated) and encapsulated active substance content should be provided. CS formulations may have slow or controlled-release properties, or may be intended to enhance operator safety or prevent impact on non-target crops for volatile actives. In the case of slow or controlled release formulations the release rate should also be provided. A test method for CS release rate may be product-specific. For slow or controlled release capsule suspension formulations the stability of free and encapsulated active substance in the spray tank over a period of time that is appropriate to cover a typical application period of the product in the field at the required in-use concentration is also required. Consideration should also be given to the release rate of the active from the capsule once sprayed i.e. *in situ*.

If more than one active substance is encapsulated, limits and levels of the free and encapsulated active substance must be provided for each active. Methods for determination of free active substance and release rate may be product-specific. Full details are included in the tables outlining the physical, chemical and technical properties in Appendix 1.

The concentrations should be expressed as follows:

- For solids, aerosols, volatile liquids (maximum boiling point 50 °C) or viscous liquids (lower limit 1 Pa.s at 20 °C), as % w/w and g/kg,
- For other liquids/gel formulations, as % w/w and g/L or g/kg,
- For gases, as % v/v and % w/w.

The tolerance limits of the active substance content normally take into account only manufacturing, sampling and analytical variations and refer to the mean analytical result obtained. The following guideline tolerances as accepted by the Manual on development and use of FAO and WHO specifications for pesticides[1] are applicable. Where the proposed tolerance limits for an active substance are outside the above ranges then this must be fully justified. For blends of granules or powders (e.g. WG formulation A blended with WG formulation B), expanded tolerances for active substance content as described in the Manual on development and use of FAO and WHO specifications for pesticides are acceptable.

[1] Manual on development and use of FAO and WHO specifications for pesticides, 2016 3rd revision of the 1st edition and any additional supplements.

Declared content in g/kg or g/L at 20 °C ± 2 °C	**Tolerance**
up to 25	± 15 % of the declared content for homogeneous formulations (EC, SC, SL, etc.) ± 25 % of the declared content for heterogeneous formulations (GR, WG, etc.)
above 25 up to 100	± 10 % of the declared content
above 100 up to 250	± 6 % of the declared content
above 250 up to 500	± 5 % of the declared content
above 500	± 25 g/kg or g/L of the declared content
Note – In each range the upper limit is included.	

Positive deviations from the upper limit (overage) are not permitted according to Regulation (EC) No. 1107/2009.

The maximum content of any relevant impurities in the plant protection product must be expressed as g/kg or g/L of the formulation.

1.4.2 Information on the active substance(s)

For active substances their ISO common names or proposed ISO common names, their CIPAC numbers, and, where available, their EC numbers should be provided.

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1.4.3 Information on safeners, synergists and co-formulants

The information on co-formulants must include:

i) Trade name;

ii) Chemical name (according to Regulation (EC) No. 1272/2008, IUPAC and CAS);

iii) CAS number;

iv) EC number;

v) Structural formula, chemical description (single substance/mixture)

vi) Function;

vii) Safety data sheets.

Safety data sheets should be up to date, fully applicable to the formulant and in accordance with Regulation (EC) No. 1907/2006 (REACH) and Regulation (EC) No. 1272/2008 (CLP). Ideally safety data sheets submitted to the evaluating Member State should be less than 2 years old; however, if the supplier does not update the MSDS this frequently, a statement may suffice.

The information submitted for each preparation component must be sufficient to chemically characterise that component, for example, for polyethoxylated components the information should include the degree of ethoxylation and the number of mole equivalents of ethylene oxide.

Where a co-formulant is itself a mixture, full details of the composition must be submitted. In cases where this information is not available to the applicant for confidentiality reasons, suppliers should be requested to deliver this data directly to the evaluating authority.

For a capsule suspension formulation, the starting materials for the capsule should be given, along with all other co-formulants in the preparation.

A description of the formulation process should be provided. This information is required as it is critical to the physical, chemical and technical properties of the formulation; for example, for granular preparations whether the active substance is incorporated into the granule or sprayed on the surface of the granule can impact on the properties of the preparation.

Equivalent co-formulants and changes in the chemical composition of a preparation

Where alternative trade names for co-formulants are given, the components must be identical in chemical composition. Separate guidance is available for changing the chemical composition of a preparation under SANCO 12638/2011. The guidance document outlines the procedures to follow under Regulation (EC) No. 1107/2009 and gives the criteria for acceptable compositional changes.

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1.5 Type and code of the plant protection product

The type of preparation should be provided according to the codes listed in the latest edition of the Technical Monograph no. 2 by CropLife International. If a particular preparation type is not defined precisely in this publication then a full description of its physical nature and state should be provided, together with proposals for a suitable description and for the critical physical, chemical and technical properties.

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2 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

Data must be submitted in the form of test reports with full details of the methods used and an explanation and justification of any deviation from standard method protocols. Reports should identify the name and batch of the preparation tested. Where the composition of the tested preparation differs from that for which authorisation is sought then this must be fully justified.

Good Laboratory Practice (GLP)

Tests and analyses shall be conducted in accordance with the principles laid down in Directive 2004/10/EC of the European Parliament and of the Council where testing is done to obtain data on the properties or safety with respect to human or animal health or the environment.

Full details of GLP requirements for specific studies are given in Commission Document 7109/VI/94 Rev 6. It is the current understanding that the requirements outlined in this document are still applicable under Regulation (EC) No. 1107/2009 until a decision is made otherwise.

It should be noted that where individual tests have a GLP requirement this still applies in the context of a storage stability study for which overall there is no GLP requirement. GLP is required for active substance / impurity determination where hazardous compounds may be formed on storage.

Where conducting studies to GLP is not possible, they may be accepted if they are considered scientifically valid and a justification is provided.

A GLP certificate for the test facility should be provided. The certificate dates must be relevant to the date(s) when the study was conducted.

Analytical Methods

Active substance and relevant impurity content

For the determination of active substance content and relevant impurities (if appropriate, see section 2.7), the methods used must be fully reported and validated. Additional guidance on method validation can be found in the most recent version of the European Commission guidance document SANCO/3030/99. A CIPAC method may be used where available; for formulation types covered by the CIPAC method, only data on specificity need to be provided. The CIPAC method can also be applied to a different formulation type, but in this case the method would require full validation data in accordance with SANCO/3030/99.

The chemical assay method used to determine the content of active substance(s) linked to a physical, chemical or technical property (such as suspensibility) must be validated according to Regulation (EU) No. 284/2013. This method could be the same method as used to determine the active substance(s) content in the formulation, provided it is fully validated at an appropriate concentration range.

For non-racemic mixtures of stereoisomers, or when the stereoisomers do not have the same biological activity, a method capable of separating and quantifying the isomers

of the active substance is required. This is to ensure compliance with the identity of the active substance established for approval or to establish the isomeric ratio conforms to the ratio established in the specification of the technical material.

The use of a method to separate the isomers may also be required for the storage stability studies to ensure the isomers are stable on storage. However, where evidence is presented that the isomeric ratio cannot change during storage, (e.g. non-racemisable isomers), separation and quantification of the individual isomers following storage will not be required.

For racemic mixtures of stereoisomers or when the stereoisomers have the same biological activity a method for separation is not required.

Physical, chemical and technical properties

The methods used for the determination of physical properties should be in accordance with the requirements of Commission Communication 2013/C 95/02 and be standard internationally recognised or ring tested methods such as CIPAC[2] methods, the 'EC methods' (Regulation (EC) No. 440/2008), OECD methods, UN RTDG Manual, ASTM or ISO. The methods referenced in this document reflect the Commission Communication at the time of writing, however new or updated internationally recognised or ring tested methods may be applicable as they become available.

For a number of properties more than one recommended method is listed. It is not expected that all methods are used, but instead the most appropriate method chosen from the list. It should be noted that when an EC test method gives a negative result, it is acceptable to assume the same result will also be obtained with the UN test method. In comparison, when a positive result is achieved using an EC test method, this cannot be easily translated into a CLP classification (due to differences in classification criteria between EC and UN test methods) and therefore a UN test method would be required. In this guidance document, CIPAC MT methods will be referenced as the appropriate MT number, e.g. CIPAC MT 75.3 ⇒ MT 75.3.

CIPAC periodically conducts a review of the methods developed under the auspices of CIPAC to take into account that older methods become obsolete or superseded and also to take into account advances in technology. A negative list of methods declared as 'obsolete' or 'superseded' is published on the CIPAC website.

However, methods which are 'no longer supported' by CIPAC may still be considered fit for regulatory purposes,[3] depending upon when the study was conducted and whether the data meet the regulatory need. Methods no longer supported are not included in this guideline.

[2] CIPAC Methods are published in the CIPAC Handbooks, details are available from www.cipac.org/

[3] Refer to http://www.cipac.org/obsolet_methods.htm for the list of methods 'no longer supported' by CIPAC

Where methods other than those specified are used they must be fully described and their relationship to the appropriate CIPAC method justified. If no CIPAC or other recognised method is available to determine a particular property, then an 'in-house method' may be acceptable providing appropriate validation data demonstrating the applicability, repeatability and robustness of the method are submitted.

If test results do not meet the acceptable criteria, this will not necessarily mean that an authorisation cannot be granted. The technical characteristics are assessed using laboratory based tests which have limitations. In some cases, it may be more appropriate to demonstrate how the formulation behaves under the intended conditions of use. For example, if the formulation does not meet the acceptance criteria for the suspensibility test (CIPAC MT 184) then a sprayability test should be conducted. In the sprayability test the formulation would be used as intended and samples collected at various intervals and analysed for the active content, using a validated method, to determine if the formulation is homogenous on application. For results that are marginally outside the criteria of acceptance appropriate label phrases may mitigate concerns. For example 'shake before use' may be appropriate if a small amount of separation is observed upon storage but the observation is fully reversible after agitation.

Ready to use preparations

The data required are the same as those for the more concentrated preparation type e.g. if the preparation is a ready to use oil in water formulation, the data for the EW formulation type must be provided. Generally, the tests required to demonstrate acceptable performance of the product when diluted in the spray tank e.g. persistent foam will not be required as the products are already diluted. However the data submitted must show that the preparation is homogeneous and can be satisfactorily applied according to the label instructions. For example, for ready to use suspensions evidence must be supplied showing the preparation is homogeneous on application.

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Physical, chemical and technical properties of the plant protection product

2.1 Appearance

Physical state

This should be described in qualitative terms such as solid, liquid, gel, gas, etc.

GLP - No

Colour

No method is specified but the following may be appropriate:

ASTM 'Standard method for of specifying colour by the Munsell system D-1535'

ASTM 'Standard method for of specifying colour of transparent liquids (Gardner Colour Scale), D-1544'

However a visual description of colour is also acceptable.

GLP - No

2.2 Explosive properties and oxidising properties

2.2a Explosive properties

Method A14 of Regulation (EC) No. 440/2008

United Nations Recommendations on the Transport of Dangerous Goods (UN RTDG) Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 6 – Part I (Test series), section 11.

Solid preparations should be tested for the effect of flame, shock and friction.

Liquid preparations should be tested for the effect of flame or shock.

The tests for explosivity are designed to give results that can be evaluated directly against the criteria for classification and labelling.

The criteria for classification of a solid or liquid as explosive under CLP are as outlined in Regulation (EC) No 1272/2008.

In accordance with the criteria set out in Appendix 6 of the United Nations 'Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria', the tests do not have to be carried out if 'A case may be made that the preparation cannot be explosive if the individual components of the preparation are not classified as explosive (i.e. the active substance and the co-formulants do not contain any groups associated with explosive properties in their structures or by reference to the MSDS for all of the co-formulants and active substance, which demonstrate that they are not explosive)'. Refer to the table below for examples of chemical groups indicating explosive properties in organic material.

Structural formula	Examples
C-C unsaturation	Acetylenes, actylides, 1,2-dienes
C-Metal, N-Metal	Grignard reagents, organo-lithium compounds
Contiguous nitrogen atoms	Azides, aliphatic azo compounds, diazonium salts, hydrazines, sulfonylhydrazines
Contiguous oxygen atoms	Peroxides, ozonides
N-O	Hydroxylamines, nitrates, nitro compounds, nitroso compounds, N-oxides, 1,2-oxazoles
N-halogen	Chloramines, fluoroamines
O-halogen	Chlorates, perchlorates, iodosyl compounds

Alternatively classification may be made through the determination of the thermal characteristics of the preparation (Differential Thermal Analysis, Differential Scanning Calorimetry) which can provide supplementary data such as evidence of exothermic decomposition, rate of energy release etc. These data can be used to help demonstrate the thermal behaviour of a product. The DSC should confirm that the exothermic decomposition energy is < 500 J/g and the onset of exothermic decomposition is < 500 °C, for the non-classification of the formulation as an explosive. It should be stated if product is thermally sensitive or sensitive to shock or friction.

In case of positive result with EC test method, the appropriate UN test method is required to confirm classification.

GLP – Yes (for experimental determinations only)

2.2b Oxidising properties

Method	**A17**	**of Regulation (EC) No. 440/2008 for solids**
	A21	**of Regulation (EC) No. 440/2008 for liquids**
	Test O.1	**Test for oxidizing solids (Manual of tests and Criteria Part III sub-section section 34.4.1 of United Nations Recommendations on the Transport of Dangerous Goods – UN RTDG)**
	Test O.2	**Test for oxidizing liquids (Manual of tests and Criteria Part III sub-section section 34.4.2 of UN RTDG)**
	Test O.3	**Gravimetric test for oxidizing solids (Manual of tests and Criteria Part III sub-section section 34.4.3 of UN RTDG)**

The methods are not applicable to gases and materials that are explosive or highly flammable or organic peroxides.

The oxidising properties do not have to be determined if it can be shown, without reasonable doubt, on the basis of thermodynamic information that the preparation is incapable of reacting exothermically with combustible materials, or if a case can be made showing the individual components of the preparation are not oxidising. The case should meet the criteria set out in Appendix 6 of the United Nations 'Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria'. Reference can be made to the Material Safety Data Sheets and structural characteristics of the co-formulants (i.e. that the formulation does not contain Cl, F or O or if it does contain Cl, F or O but these are bonded to C and/or H only). Organic peroxides are classified based on their chemical structure and on the available oxygen and hydrogen peroxide content of formulations.

A17: Burning rates of test substance and reference substance to be reported. The formulation is not oxidizing when burning rate of test substance is less than reference substance.

A21: mean pressure rise time for test substance and reference substance to be reported. The formulation is not oxidizing when time for mean pressure rise of test substance is greater than for reference substance.

The criteria for classification of a solid or liquid as oxidising under CLP are as outlined in Regulation (EC) No. 1272/2008.

In case of positive result with EC test method, the appropriate UN test method is required to confirm classification.

GLP – Yes (for experimental determinations only)

2.3 Flammability and self-heating

2.3a Flashpoint

Method A9 of Regulation (EC) No. 440/2008

This test is only required for preparations that contain flammable liquids. Only data generated using a closed cup method are considered acceptable. The method is appropriate for all liquid preparations **except aerosols**. Aerosol flammability should be tested in accordance with the methods described in Annex I, Part 2.3 of Regulation (EC) No. 1272/2008 and classified accordingly.

The preparation is classified as 'H224: Flammable liquid 1' where the flashpoint is < 23 °C and the boiling point ≤ 35 °C.

The preparation is classified as 'H225: Flammable liquid 2' if the flash point is < 23 °C and the boiling point > 35 °C.

Preparations are classed as 'H226: Flammable liquid 3' where the flashpoint is ≥ 23 °C but ≤ 60 °C.

The test is not required if a case can be made showing the individual components of the preparation are not flammable. The case should meet the criteria set out in Appendix 6 of the United Nations 'Recommendations on the Transport of Dangerous

Goods, Manual of Tests and Criteria'. Reference can be made to the Material Safety Data Sheets.

GLP – Yes (for experimental determinations only)

2.3b Flammability

Method	**A10**	**of Regulation (EC) No. 440/2008 for solids**
	A11	**of Regulation (EC) No. 440/2008 for gaseous materials**
	A12	**of Regulation (EC) No. 440/2008 for contact with water**
	Test N.1	**test method for readily combustible solids (Manual of tests and Criteria Part III sub-section 33.2.1 of UN RTDG)**

Data according to method A12 are only required if the preparation is designed to liberate a gas on contact with water or if data on the active substance or co-formulants show the individual components may release a gas on contact with water.

Solid preparations are classified as 'flammable' if they readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition. The following classifications are proposed under Regulation (EC) No 1272/2008 (CLP):

Classification category	Criteria
1: Danger, flammable solid (H228)	Burning rate test Substances and mixtures other than metal powders: (a) wetted zone does not stop fire and (b) burning time < 45 seconds or burning rate > 2.2 mm/s Metal powders: burning time ≤ 5 minutes
2: Warning, flammable solid (H228)	Burning rate test Substances and mixtures other than metal powders: (a) wetted zone does stops the fire for at least 4 minutes and (b) burning time < 45 seconds or burning rate > 2.2 mm/s Metal powders: burning time > 5 minutes and ≤ 10 minutes

Gaseous substances and preparations are classified as 'Flammable' (H220: extremely flammable gas or H221: flammable gas) if they are flammable in contact with air at ambient temperature (20 °C) and standard pressure (101.3 kPa).

For gases the lower explosion limit (LEL) and the upper explosion limit (UEL), or a statement that the gas is non-flammable over a full range of mixtures with air, must be submitted. The lower and the upper explosion limits are those limits of concentration of the flammable gas in admixture with air at which propagation of a flame does not occur.

The test is not required if a case can be made showing the individual components of the preparation are not flammable. The case should meet the criteria set out in Appendix 6 of the United Nations 'Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria'. Reference can be made to the Material Safety Data Sheets.

In case of positive result with EC test method, the appropriate UN test method is required to confirm classification.

GLP – Yes (for experimental determinations only)

2.3c Self-heating

Method	**A15**	**of Regulation (EC) No. 440/2008 for liquids and gases**
	A16	**of Regulation (EC) No. 440/2008 for solids**
	Test N.4	**test method for self-heating substances (Manual of tests and Criteria Part III sub-section 33.3.1.6 of UN RTDG)**

According to A15 the self-ignition temperature for liquids and gases is the lowest temperature at which the preparation will ignite when mixed with air under defined conditions.

According to A16 the self-ignition temperature for solids is the temperature of the oven at which the sample temperature reaches 400 °C by self-heating.

When using Test N.4 the classification is in accordance with CLP. The criteria for classification of a self-heating substance/mixture are as outlined in Regulation (EC) No. 1272/2008.

In case of positive result with EC test method, the appropriate UN test method is required to confirm classification.

GLP – Yes

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2.4 Acidity/alkalinity and pH value

2.4a pH

Method	**MT 75.3**	**Determination of pH values**

For solid and liquid preparations to be applied as aqueous dilution the pH of a 1 % aqueous dilution, emulsion or dispersion of the preparation should be determined.

In the case of aqueous preparations, the pH value of the neat preparation should also be determined.

The temperature that the pH was determined at should be reported.

GLP – Yes

2.4b Acidity/alkalinity

Method	**MT 191**	**Acidity or alkalinity of formulations**
	MT 31	**Free acidity or alkalinity**

MT 191 is the preferred method.

The acidity or alkalinity should be tested if the preparation has pH < 4 or pH > 10 (for either 1 % dilution or neat formulation). The test expresses free acidity or alkalinity calculated as % H_2SO_4 or % NaOH.

The pH only gives an indication of the ionisation of strong acids/bases. The acidity/alkalinity gives the total concentration of weak and strong acids/bases and hence is used to assess corrosive nature of formulations.

GLP – Yes

2.5 Viscosity and surface tension

2.5a Viscosity[⊕]

Method	**OECD**	**Test guideline No. 114**
	MT 192	**Viscosity of liquids by rotational viscometry (dynamic viscosity)**
	MT 22	**Viscosity (kinematic viscosity)**

Non-Newtonian liquids:

[⊕] note :- the lowest dynamic viscosity of liquids occurring at room temperature is approximately 0.2 mPa.s (1 mPa.s = 1 cP)

The dynamic viscosity is required for all non-Newtonian liquids and the results should be reported with full details of the test methodology. The viscosity shall be determined at a minimum of two shear rates. All tests must be conducted at 20 °C and 40 °C.

Only the rotational viscometer can be used for determination of the dynamic viscosity of liquids. CIPAC method MT 192, based on OECD 114, is the preferred method. CIPAC MT 192 requires at least two shear rates to be reported, beginning with the lowest one. Unless otherwise specified, shear rates within the range of 20 to 100 s^{-1} are recommended.

Newtonian liquids:

The viscosity is required for all Newtonian liquids and the results should be reported with full details of the test methodology. The viscosity must be determined at 20 °C and 40 °C. Dynamic viscosity can be converted to kinematic viscosity as follows:

$$\frac{\text{Dynamic viscosity (mPa.s)}}{\text{Density (g/cm}^3\text{)}} = \text{Kinematic viscosity (mm}^2\text{/s)}$$

Note the temperature used for the determination of both dynamic viscosity and density should be identical.

Alternatively the kinematic viscosity of Newtonian liquids can be determined according to CIPAC MT 22.

Classification criteria for aspiration hazard

For a formulation that contains at least 10 % of a substance which has been classified as a Category 1 aspiration hazard (e.g. hydrocarbon) the preparation must be considered for classification as an aspiration hazard, based on the viscosity of the formulation.

Classification criteria under CLP

Under Regulation (EC) No. 1272/2008, the following hazard category *for mixtures* for aspiration toxicity is proposed:

> Contains at least 10 % of a substance which has been classified as a Category 1 aspiration hazard (e.g. hydrocarbon) and which has a kinematic viscosity of ≤ 20.5 mm^2/s measured at 40 °C
>
> If a mixture is split into 2 layers whereby one of the layers is classified as Category 1 aspiration hazard as detailed above then the whole mixture shall be classified in Category 1 (hazard statement H304). This criterion applies to all preparations where separation is observed either prior to or following storage.

Note: For classification according to Regulation (EC) No. 1272/2008, the surface tension is not used to determine whether the product is an aspiration hazard - however these data are still required, see 2.5b.

GLP – Yes

2.5b Surface tension

Method	**A5**	**of Regulation (EC) No. 440/2008**
	OECD	**Test guideline No. 115**

The surface tension shall be determined at the highest in use concentration. If the surface tension is below 60 mN/m, the product is surface active.

GLP – Yes

2.6 Relative density and bulk density

2.6a Relative density

Method	**A3**	**of Regulation (EC) No. 440/2008**
	OECD	**Test guideline No. 109**

The specific method (from A3) must be appropriate to the preparation type.

The relative density of a liquid plant protection product should be determined and reported. Determination of the density in g/L at 20 °C is also accepted.

GLP – Yes

2.6b Bulk (pour and tap) density

Method	**MT 186**	**Bulk density**

The pour and tap density of powder and granular formulations should be reported.

GLP – No

DRAFT

2.7 Storage stability and shelf-life: effects of temperature on technical characteristics of the plant protection product

Data are required to demonstrate the stability of the active substance and the physical-chemical and technical characteristics of the preparation on storage. Accelerated data and data from storage at ambient temperatures (shelf-life) must be submitted, but data from accelerated testing can give a useful indication of the stability, and may be extrapolated to propose a shelf life for the product, with the proviso that shelf-life data are subsequently provided to support the proposal. More detailed comments on temperature regimes for accelerated and ambient studies follow in the paragraphs below. Additionally, in the case of liquid preparations, the effect of low temperatures on stability must be provided. For capsule suspensions this should be carried out as temperature cycling (i.e. freeze/thaw) instead of cold stability testing to MT 39.3 to demonstrate that capsule integrity is not adversely affected. For some formulations use of the phrase 'protect from frost' on the product label may be acceptable *in lieu* of cold stability test data. For other formulations either a more detailed reasoned case or test data will be required (see Section 2.7.2 Cold Stability Testing for further information).

General considerations for storage stability

The active substance content and the relevant physical, chemical and technical characteristics of the product must be determined before and after storage. The stability tests must be carried out on the same sample (i.e. same lot or batch) before and after storage.

With respect to relevant impurities, storage stability data are only required where the relevant impurity may form upon storage of the product or during manufacture of the formulation. In these cases the content of the relevant impurity should be determined before and after storage. Impurities from manufacture of the active substance i.e. process impurities that are controlled within the technical specification, and for which a scientifically valid justification can be provided to support the case that they will not form upon storage of the formulation, do not need to be determined. A method of analysis for such impurities is still required however, since a method must be available to monitor levels of relevant impurities in formulations post-registration for compliance purposes.

It is recognised that a loss of up to 5 % of the active substance is unlikely to adversely affect the safety or efficacy of the preparation. In either accelerated or ambient temperature storage stability studies, where a loss of > 5 % of the active substance occurs then the fate of the active substance must be addressed and the breakdown products identified. For preparations in which the active substance content is relatively low (< 25 g/kg or g/L) losses of > 5 % *may* be less significant in terms of breakdown products. In such cases the apparent fate of the active substance must still be addressed but reasoned cases *may* suffice. All such instances will necessarily be treated on a case by case basis.

Where a loss of ≥ 10 % of the active substance occurs during the accelerated study, in addition to the points above, ambient shelf-life data from interim time periods e.g. 3, 6, 12 months should also be submitted to address the kinetics of breakdown and establish an appropriate shelf life for the product.

It should be noted that a change in the concentration of the active substance on storage due to degradation is distinct from the active substance tolerance limits as described in section 1.4.1. Even if the loss does not result in exceedance of the tolerance limits, any loss of greater than 5 % still needs to be addressed.

Although it is fully acceptable to collect data at T0 and T24 only when conducting a 2 year ambient storage stability study, it is worthwhile considering collection of data at interim time points e.g. at three month intervals, in order to collect a more thorough dataset to understand the effects of storage. Furthermore, in line with the comment above for accelerated storage, if ≥ 10 % loss of active substance content occurs upon ambient storage, the active substance content at interim time periods e.g. 3, 6, 12 months should be submitted to address the kinetics of breakdown and establish an appropriate shelf life for the product, therefore in this instance collection of data at T0 and T24 only would not be acceptable.

It is recognised that on storage, plant protection products may undergo changes which will be dependent on the active substance, the preparation, container and the conditions of storage. Such changes may be acceptable if they have no adverse effect on the operator, consumer or environmental safety, the application or the biological performance. Where there is a significant change in the physical characteristics of the preparation e.g. suspensibility then the relevance of the change must be discussed and if necessary labelling proposals made.

Where a repellent has been added to a preparation e.g. to reduce risk to non-target species, then the storage stability testing should also demonstrate retention of repellency.[4] This may be achieved through analytical determination of the levels of the repellent if achievable, or through demonstration that the efficacy of the repellent is retained before and after storage.

Packaging for stability tests

Storage stability tests should be performed in the commercial packaging or the material of which the commercial pack is to be manufactured; however, glass may be used in the accelerated tests as outlined in the relevant CIPAC MT methods.[5] In all cases the proposed commercial packaging must be declared. See Section 4 for further details of extrapolations between packaging types.

[4] It is noted that stability of repellents is not a formal requirement under Commission Regulation (EU) No. 284/2013; however, it is included in this guidance for good practice as loss of repellency may have a direct impact on safety.

[5] The EU PPP data requirements (stated in Commission Regulation (EU) No. 284/2013) which are valid from 1st January 2016, state that '*Consideration shall be given to performing this test in packaging made of the same material as the commercial packaging*'.

Accelerated testing

Method MT 46.3 Accelerated storage procedure

Accelerated tests are performed at elevated temperatures to ensure that the properties of formulations are not adversely affected by storage at high temperature and to assess the long term storage stability in a short time frame. However, it is accepted that preparations are complex mixtures and elevated temperatures may initiate a reaction which may not occur under 'normal' conditions of storage. Unless a preparation is shown to be very stable under all conditions, care must be exercised in the interpretation of results from such tests.

Accelerated storage data may be extrapolated to propose a shelf life for the product, with the proviso that shelf-life data are subsequently provided to support the proposal.

The usual storage regime for accelerated tests is 2 weeks at 54 °C (± 2 °C); however, some preparations may not be stable under these conditions and alternative time/temperature regimes may be used:

Temperature (± 2 °C)	Time (weeks)
54	2
50	4
45	6
40	8
35	12
30	18

Alternative time/temperature regimes may be proposed but the choice must be supported by a reasoned, scientific case.

GLP is not an overall requirement for storage stability studies; however, as part of the determination of technical characteristics of the preparation, GLP is required for certain individual tests carried out within a storage stability study, e.g. pH. GLP is required for active substance determination only where relevant impurities or other hazardous compounds may be formed on storage. To meet the GLP requirements for individual tests it may be advantageous to carry out all tests within the storage stability study in a GLP test facility.

Where accelerated testing shows a significant change in active substance content or physical characteristics, then results from ambient temperatures must demonstrate that, under 'normal' conditions of storage, the preparation retains acceptable active substance content and physical characteristics.

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Cold Stability testing

Method MT 39.3 Low temperature stability of liquid formulations

Liquid preparations where the active substance or preparation may crystallise, or where phase separation could occur should also be tested at 0 °C or lower. For capsule suspensions (CS, ZC, ZW, ZE), the effects of low temperature should be carried out as temperature cycling (i.e. freeze/thaw). Unless otherwise agreed, the freeze/thaw stability test shall cycle the formulation between room temperature (e.g. 20 ± 2 °C) and -10 ± 2 °C on 18-hour-freeze/6-hour-melt cycles for a total of 4 cycles, in order to demonstrate that capsule integrity is not adversely affected.

Appropriate technical characteristics of the preparation which may be adversely affected by low temperatures should be determined after storage. These will often be related to the precipitation or separation of liquid phases. If an effect is observed during the test e.g. phase separation, then the reversibility of this must be addressed. The requirements are shown for the individual preparation types in Appendix 1.

Where the preparation is adversely affected by freezing conditions, but it is judged upon evaluation by the regulatory authority that the product can still be applied safely and efficaciously, then this should be indicated and the phrase 'protect from frost' must be included on the label.

GLP – No

Ambient testing (shelf-life)

Real-time and ambient temperature testing is performed under ‘normal conditions’, usually over a period of 2 years. The results produced give a more accurate description of the likely properties and do not require extrapolation. However, such tests require a prolonged testing period. These tests are also the most appropriate in producing information on the stability of the packaging for a product.

The tests should be conducted at ambient temperature or, 20 °C, 25 °C or 30 °C dependent on the expected geographical areas of use.

Storage temperatures must reflect the maximum and minimum temperatures likely to be experienced in a warehouse, farm store or garden store for amateur products. Where tests are not conducted under typical storage conditions, then the temperature used during the storage period must be justified and recorded during the study.

For laboratory tests, the following values are appropriate for different climatic regions:

Moderate/temperate climate	18 – 22 °C
Hot climate	23 - 27 °C
Very hot climate	28 – 31 °C

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In line with the CropLife International (formerly GIFAP) Monograph 17 2nd Edition,[6] it is recommended that studies are conducted at 20 °C (or the nearest ambient temperature).

The data submitted must support the proposed shelf-life of the preparation. It is normally expected that a preparation should have a shelf life of at least two years. This is based on the premise that a preparation may be purchased for use in one season but not be used up in that season and kept to the following year or next season. Where a preparation has a shelf life of less than 2 years, this must be fully justified and the label must identify the manufacturing date and the 'use by' date. Under these circumstances the applicant should address the disposal of any unused product.

Following storage of the packaging any changes in the pack such as panelling, ballooning, condition of seals and seams and weight change must be reported in detail.

GLP is not an overall requirement for ambient storage studies. However, as part of the determination of technical characteristics of the preparation, GLP is required for certain individual tests carried out within an ambient storage study, e.g. pH. GLP is required for active substance determination only where relevant impurities or other hazardous compounds may be formed on storage. To meet the GLP requirements for individual tests it may be advantageous to carry out all tests within an ambient storage study in a GLP test facility.

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[6] Available from the CropLife website (https://croplife.org/wp-content/uploads/2014/05/Technical-Monograph-17-2nd-edition-June-2009.pdf)

2.8 Technical characteristics of the plant protection product

The properties required are in accordance with Regulation (EC) No. 1107/2009, Regulation (EU) No. 284/2013 and the Manual on development and use of FAO and WHO specifications for pesticides[7]. In this guidance document the technical characteristics for specific formulation types are presented in Appendix 1. Those properties which must be determined before and after storage are indicated. The appropriate limits for each property are described in this section.

Where a test is not considered applicable to a particular preparation then this must be explained and justified.

Where information is not given on a specific formulation type then a logical approach should be taken addressing the appropriate properties and using the relevant tests. This also applies to mixed formulation e.g. ZC, ZE and ZW.

Tests of physical properties cannot replicate what happens in the field under all circumstances. Instead, the tests provide simple models against which satisfactory/unsatisfactory performance may be judged. Test results are therefore indicative of physical performance; they do not define exactly how a product will perform under specific conditions.

For some physical, chemical and technical tests, recommended limits are stated. For example, in the case of suspensibility, not less than 60 % of the active substance shall remain in suspension. Where individual tests give adverse results further field tests will be required to demonstrate that the preparation can be effectively applied. For example this may take the form of a sprayability study. Additional studies should reflect worst case conditions of use according to Good Agricultural Practice.

In some test methods the test results may be described in relatively subjective terms such as 'trace of sediment'. In these circumstances the study reports, where possible, should supply quantitative estimates based on (at least) a visual inspection and fully describe the appearance of any sediment etc.

CIPAC Standard Water

The physical properties of formulations that are diluted with water before use can be affected by the hardness of the water used for dilution. CIPAC Handbook F lists standard waters that may be used in laboratory tests,[8] to simulate naturally occurring waters.

With certain exceptions, Standard Water D (representing standard hard water) should be adopted in tests, even where an alternative Standard Water is recommended in the CIPAC method. Exceptions are tests of emulsion stability and dispersion stability where both Standard Waters A and D are to be used, since these properties may be affected by soft water as well as hard water.

The type of water used must be clearly indicated for all tests.

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[7] Manual on development and use of FAO and WHO specifications for pesticides, 2016 3rd revision of the 1st edition and any additional supplements.

[8] Preparation of Standard Waters A to D are described in CIPAC methods MT 18.1.1 to MT 18.1.4.

Test concentrations

The test methods provide information on how to conduct the tests and may also give concentrations of product at which the tests should be conducted. In order to ensure that the product will perform acceptably when used in the field the concentration of the product tested for each technical property should relate to the recommended use rates given on the label, so long as the concentration used is within the scope of the method.

Where several use rates are recommended, the highest and lowest concentrations should be used so long as they are within the limitations of the test method, however some tests may not need to be conducted at both the high and low concentrations, where a clear 'worst case' dilution can be identified. Where a fixed concentration is specified by the test method, this concentration should be used.

The following table is an example of typical concentrations to be tested but is not exhaustive. If alternative test concentrations are used these may be accepted if supported by scientific justification.

Where a product is applied undiluted only, tests that require a dilution are not appropriate. For example, it is recognised that for seed treatments the concentrations at which they are applied to seeds significantly exceed those for field application of pesticides. Therefore a justification may be submitted that certain tests are not required.

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Recommended concentrations for use in physical, chemical and technical property tests

Formulation types	Parameter CIPAC method	Concentration to be tested
Water soluble products (SL)	Dilution stability MT 179.1 MT 41.1 MT 196	Highest recommended concentration within scope of the method; (for MT 179.1 the minimum concentration is 3 g in 250 mL)
Preparations which form emulsions	Emulsion stability MT 36.3	Highest and lowest recommended concentration; (within the scope of the method; 0.1 % to 5 %)
Preparations which form dispersions (e.g. SE)	Dispersion characteristics MT 180	Highest and lowest recommended concentration
Preparations to be diluted with water	Persistent foam MT 47.3	Highest and lowest recommended concentration
Water dispersible products (WG, SC)	Spontaneity of dispersion MT 160 MT 174	Fixed concentration in line with the methods: For MT 160; 12.5 mL in 250 mL For MT 174; 9 g in 900 mL
Water dispersible products (WP, WG, SC)	Suspensibility MT 184	Highest and lowest recommended concentration but not lower than 0.2 % as this is outside the scope of the method.
WP, SG, WG	Wettability MT 53.3	Fixed concentration in line with the method 5 g in 100 mL
Preparations forming a suspension when diluted with water	Wet sieve MT 185	Highest recommended concentration
-	Dissolution of water soluble bags MT 176	Fixed concentration in line with the methods 50 x 100 mm from the bag material 10 g of the corresponding powder in 1000 mL

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2.8.1 Wettability

Method **MT 53.3** **Wetting of wettable powders**

Wettability is determined to ensure the preparation is readily wetted in use. The data are required for solid preparations which are to be dispersed in water.

The method as written describes the wetting of wettable powder preparations but it is also applicable to water soluble powders, water soluble granules and water dispersible granules.

Acceptable limits :-	A preparation is considered acceptable if there is complete wetting in 1 minute without swirling. If the criterion is met without swirling then performance of the test with swirling is not required.
Where a preparation is outside this limit then evidence must be submitted demonstrating acceptable wetting in the spray tank or other application equipment	

GLP – No

2.8.2 Persistent foaming

Method **MT 47.3** **Persistent foam**

Persistent foam is determined to measure the amount of foam likely to be present in a spray tank or other application equipment following dilution of the preparation.

Acceptable limits :-	Max 60 mL foam after 1 minute
Where a preparation is outside these limits then evidence must be submitted showing that there is no unacceptable risk to operators following use of the preparation through the appropriate application equipment.	

GLP – No

2.8.3 Suspensibility, spontaneity and dispersion stability

2.8.3a Suspensibility and dispersion stability

Method **MT 184** **Suspensibility of formulations forming suspensions on dilution with water**

MT 180 **Dispersion stability of suspo-emulsions**

Suspensibility/dispersion stability is determined to demonstrate that a sufficient amount of the active substance is suspended in the spray liquid to give a satisfactory, homogeneous mixture during spraying.

For the determination of suspensibility using CIPAC MT 184, chemical assay ('active' suspensibility) is the only fully reliable method to measure the mass of active substance still in suspension. However, gravimetric determination (total suspensibility) or solvent extraction determination may be used providing that these methods have been shown to give equivalent results to those of the chemical assay.

Where there is more than one insoluble active substance present in the preparation, chemical assay ('active' suspensibility) is the only acceptable method. Full validation data should be submitted to support the analytical method in accordance with Regulation (EU) No. 284/2013.

Acceptable limits :-	MT 184 The mean measured active suspensibility must not be less than 60 % or greater than 105 %. MT 180 If any separation observed, re-dispersion should be complete after 24 hours. If the concentration tested is equivalent to the fixed concentration in the CIPAC method, i.e. 5 g in 240 mL, 2 mL cream and a trace of oil are acceptable limits. These limits are dependent on the concentration tested, therefore further consideration of acceptable limits may be required if different concentrations are tested.
Where a preparation is outside these limits then evidence must be submitted demonstrating that the preparation is homogeneous on application through appropriate application equipment e.g. determination of active substance content in the spray at the beginning, middle and end of a spraying operation at highest and lowest use rates on the label. Observations on any nozzle blockages should also be included.	

GLP – No

2.8.3b Spontaneity of dispersion

Method	**MT 160**	**Spontaneity of dispersion of suspension concentrates**
	MT 174	**Dispersibility of water dispersible granules**

The spontaneity of dispersion is determined to show the preparation is rapidly dispersed when diluted with water.

As for the determination of suspensibility, chemical assay ('active spontaneity') is the only reliable means to measure the mass of active substance in dispersion in the spontaneity test according to MT 160. For the determination of spontaneity according to MT 174, gravimetric assay is prescribed.

Gravimetric determination or solvent extraction determination may be used on a routine basis providing that these methods have been shown to give equivalent results to those of the chemical assay.

Where there is more than one insoluble active substance present in the preparation, chemical assay is the only acceptable method. Full validation data should be submitted to support the analytical method in accordance with Regulation (EU) No. 284/2013.

Acceptable limits :-	The mean measured minimum active spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %.
	Where a preparation is outside these limits then evidence must be submitted demonstrating that the preparation is homogeneous on application through appropriate application equipment with no blockages.

GLP – No

2.8.4 Degree of dissolution and dilution stability

Method	**MT 179.1**	**Degree of dissolution and solution stability**
	MT 41.1	**Dilution stability of aqueous solutions**
	MT 196	**Solution properties of water soluble tablets**

The scope of MT 179.1 states the method applies to water soluble granules only, however it has been agreed by CIPAC that the method is also applicable to water soluble powders (SP and SS). The method MT 196 only applies to water soluble tablets.

The dilution stability is determined to ensure that water-soluble preparations dissolve readily and/or, when diluted, produce stable solutions without precipitation, flocculation, etc. The results submitted should fully describe the appearance and amount of any separation or sediment.

Acceptable limits :-	MT 41.1 'trace' of sediment after 30 minutes – the amount and appearance of any sediment should be fully described.
	If any material has separated after 24 hours determine the amount of residue on a 75 µm sieve according to a procedure adapted from MT 185 (b) Wet Sieving and the content of the active substance in this residue.
	MT 179.1 max 2 % on 75 µm sieve
Where a preparation is outside this limit then evidence must be submitted showing the material separated will not block application equipment or present	

an unacceptable risk to the operator or lead to unacceptable residues or crop safety concerns.

GLP – No

2.8.5 Particle size distribution, dust content, attrition and mechanical stability

2.8.5.1 (a) Wet sieve test

Method **MT 185** **Wet sieve test**

A wet sieve test is required for water dispersible products. The residue remaining on a sieve is determined after dispersion to ensure no unacceptable residue remains which might cause the blockage of nozzles or filters on application equipment.

Acceptable limits :-	Maximum 2 % retained on a 75 µm sieve. Where a preparation is outside this limit then evidence must be submitted showing the preparation may be satisfactorily applied through appropriate application equipment with no blockages.

GLP – No

2.8.5.1 (b) Particle size distribution

Method **MT 170** **Dry sieve analysis of water dispersible granules**

MT 187 **Particle size analysis by laser diffraction**

The nominal size range for solid materials for direct application and solid materials for dispersion in water must be determined with MT 170.

For dustable powders using method MT 170: if > 5% of the preparation is retained on a 75 µm sieve, the active substance content of the residue remaining on the sieve must be determined to demonstrate that there is no unacceptable change of the content due to potential separation of the active substance from the carrier (filler).

Where relevant the particle size of formulations classed as 'dusty' according to MT 171.1 must be determined using CIPAC MT 187.

Where a formulation is classed as 'dusty' according to MT 171.1 (2.8.5.2) and/or where a significant proportion of particles (> 1 % by weight) have a diameter of < 50 µm then inhalation toxicity data may be required.

Acceptable limits	For powder formulations: MT 170: The active substance content of material remaining on the sieve must be determined to demonstrate there was no separation of the active substance from the carrier if

	> 5 % of the preparation is retained on a 75 µm sieve. Not more than (0.005 x AI content in g/kg) % should be present as the AI in the residue on the sieve. Where more than 1 % of particles (w/w) are below 50 µm, then particle size of this dust must be determined (CIPAC MT 187) and an inhalation study may be required. For granulated formulations: Where more than 1 % are below 50 µm, then particle size of this dust must be determined (CIPAC MT 187) and an inhalation study may be required.

GLP – Yes

2.8.5.2 Dust content

Method MT 171.1 Dustiness of granular products

The dust content of solid preparations must be determined to ensure there is no unacceptable risk to operators, residents or bystanders or potential for blockage of application equipment.

MT 171.1 describes two methods for the determination of dustiness but the gravimetric method is regarded as the 'Referee' method. Where a preparation is described as 'dusty' under MT 171.1, data on inhalation toxicity may be required.

The dustiness categories for products (as stated in MT 171.1) are as follows:

Category	Range of results		Interpretation
	Gravimetric collected dust (mg)	Optical dust factor	
1	0 – 12	0 – 10	Nearly dust free
2	>12 – 30	>10 – 25	Essentially non dusty
3	>30	>25	Dusty

Acceptable limits :-	The amount of dust (either in mg for the gravimetric method or as dust value for the optical method) must be stated. Products should be 'nearly dust free' (category 1) or 'essentially non dusty' (category 2). For products that fall outside these categories the implications for the potential risk to operators, residents and bystanders must be addressed. (1) For the impact on operators, residents and bystanders the particle size and nature of the dust

	must be investigated. CIPAC Method MT 187 particle size by laser diffraction should be used to establish the particle size distribution.

GLP – Yes

2.8.5.3 Attrition resistance

Method	**MT 178**	**Attrition resistance of granules (GR)**
	MT 178.2	**Attrition resistance of dispersible granules**

Attrition is defined as the wearing away of the surface of a granule by friction or impact, particularly by granule-to-granule interaction.

These data are required to determine whether a granular material is robust under normal conditions of use and transport.

Acceptable limits :-	Where the material has an attrition resistance of < 98 % then the particle size of the dust must be determined and the risk to operators, residents and bystanders must be addressed. For granules, where the material has an attrition resistance of < 98 % then evidence is required that the material may be satisfactorily applied through application equipment.

GLP – No

2.8.5.4 Hardness and integrity

Method	**MT 193**	**Attrition of tablets**

CIPAC MT 193 method was originally titled ‘Friability of tablets’, however it was noted that the method determined the attrition of the tablets rather than the attrition resistance. The test is required in order to demonstrate that tablets do not break-up in the sales pack.

2.8.6 Emulsifiability, re-emulsifiability, emulsion stability

Method	**MT 36.3**	**Emulsion characteristics and re-emulsification properties**

The data are required to determine whether a preparation forms and maintains a stable emulsion.

MT 36.3 is designed to be conducted over a 24 hour period; however, if no separation of cream or oil is observed after 2 hours then no further testing is required. If separation is observed then the 24 hour test should be carried out.

Acceptable limits :-	MT 36.3 If any separation observed re-emulsification should be complete after 24 hours. Where a preparation shows significant levels of cream, free oil or solid matter, or where there is incomplete emulsification, then evidence must be submitted showing the preparation remains homogeneous when applied through appropriate application equipment. Precise limits for levels of cream and oil cannot be given as these will be dependent on the amount of sample used in the test.

GLP – No

2.8.7 Flowability, pourability and dustability

2.8.7a Flowability

Method	**MT 172.1**	**Flowability of granular preparations after accelerated storage under pressure**

The data are required to demonstrate that granular materials remain free flowing after storage under pressure.

Acceptable limits :-	Report whether the sample drops through the sieve spontaneously. The sample should flow through the sieve after a maximum of 5 liftings. If this is not the case, the quantity of the sample which remains on the sieve after 5 and 20 liftings should also be reported.

GLP – No

2.8.7b Pourability

Method	**MT 148.1**	**Pourability of suspension concentrates**
	MT 148	**Pourability of suspension concentrates (includes rinsed residue)**

The data are required to demonstrate that the user can make use of the maximum amount of the preparation and that an excessive amount of the material does not remain in the container. The method is appropriate to suspension concentrates, capsule suspensions, oil in water emulsions, oil dispersions and suspo-emulsions.

Acceptable limits :-	Maximum 5 % residue. Where a preparation is outside these limits then evidence is required that the residue remaining in the commercial pack following recommended rinsing procedures is acceptable (if appropriate). In these circumstances an acceptable limit would be max 0.25 % rinsed residue.

GLP – No

2.8.7c Dustability

Method MT 34 Dustability tests after tropical storage

Reference is made to the use of MT 34 although it is noted that this method is obsolete (equipment is not readily available) it is referred to as there is currently no replacement method. It is therefore acceptable for applicants to use their own equipment, provided that this is described and it is indicated that there is no unacceptable compaction or caking following a heat test under pressure.

Additionally, data are required showing the preparation may be satisfactorily applied as a dust through the proposed application equipment.

GLP – No

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2.9 Physical and chemical compatibility with other products including plant protection products with which its use is to be authorised

Tank mix compatibility

Data on physical and chemical compatibility of the preparation are required where tank mixes are recommended on the label. Tank-mixes could either be convenience tank mixes (the combination by the user of two or more PPPs (or one or more PPPs with an adjuvant) in the same spray tank to reduce the number of spray operations) or positive tank mixes (the combination by the user of two or more products in the same spray tank to obtain better pest control than if the products were applied alone).

When applying for the first authorised label-recommendation of a tank mix for a product that contains an active substance for which no tank mixes have been previously authorised in any product, data and/or reasoned scientific cases demonstrating that the product is physically and chemically compatible in the proposed mixture must be submitted. Full study reports are required. The ASTM standard method is E 1518-05. If another test method is used then it must be justified.

These data can be provided under the first application to be considered for the active substance, or any subsequent application for a product containing that active substance.

Once the first tank mixture has been authorised for any product containing that active substance, subsequent tank mixes for any products must also be supported by physical and chemical compatibility data. However, regulators do not need to see these data in full but will accept a Compatibility Assurance Statement (CAS) statement certifying that data or evidence is available to demonstrate that the products in the proposed mixture are physically and chemically compatible. Please see appendix 2 for a suggested template. The underlying data must be available for submission if requested by the regulator. A CAS must be submitted whenever a new label containing new tank-mixes is requested.

Where a product label recommends a mixture to give an enhanced effect when the tank-mix is used, in addition to the physical and chemical compatibility data described above, additional biological compatibility (efficacy) data will be required.

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2.10 Adherence and distribution to seeds

The requirements for seed treatments include the determination of the physical, chemical and technical properties of the preparation itself in addition to evidence that the preparation may be satisfactorily applied to the seed.

2.10a Loading and distribution of active substance

Active substance loading

Data are required to show a seed treatment preparation may be applied to give acceptable and uniform loading. The data will also support other areas of the risk assessment such as ecotoxicology, residues and efficacy.

The seed loading should be a determination of the active substance content of the seeds, and a validated method of analysis should be used to determine this. Where a preparation contains two active substances then data for both active substances must be submitted. Where a preparation contains more than two active substances, then loading results for two of the components may be acceptable. In this case, the active substances chosen must be representative of pesticide types present e.g. if one or more insecticides and fungicides are applied then the analysis must include one of each pesticide type.

Tests should be carried out on seed from each crop or crop group on which the preparation is proposed for use. Extrapolations may be accepted from one seed type to another on the basis of comparable seed size, shape and surface morphology.

Data from small scale laboratory machines are acceptable but because different seed treatment machines (both commercial and small scale) employ different mechanisms it is advisable to test a seed treatment using commercially available seed treatment methods. This is especially important should preliminary small scale testing show any suggestion of possible formulation/machinery problems. The data must be supported by a full description of all procedures used in the test.

GLP – No

2.10b Uniformity of distribution

Method	**MT 175**	**Determination of seed-to-seed uniformity of distribution for liquid seed treatment formulations**

The uniformity of distribution on treated seed may be determined using MT 175. This method is dependent on a dye being present in the preparation. Where a dye is not present then the uniformity of distribution may be determined by measurement of the active substance content on the seed using a validated method of analysis.

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Acceptable limits :-	seed loading	70 % of target dose
	uniformity, seed-to-seed	% RSD ± 25 %

The limits have been defined based on seeds of crops which are homogeneous in shape and size. For other seeds which differ significantly in shape and size, the limits may not be applicable.

Where the loading and/or uniformity of distribution are outside these limits a justification should be given. This could be in the form of a written explanation or data submitted showing the treatment is efficacious, for example from efficacy field trials data.

GLP – No

2.10c Adhesion

Method **MT 194** **Adhesion to treated seeds**

European Seed Association, 2011. Assessment of free floating dust and abrasion particles of treated seeds as a parameter of the quality of treated seeds: Heubach test. ESA STAT Dust Working Group.

The method MT 194 determines the amount of product retained on treated seed after the seed falls from a funnel for a set distance. The method is not designed to classify or reliably quantify the part of the seed treatment product that is not retained on the seeds. The method is applicable to cereals, maize and sunflower seeds. It applicability to other seed types must be carefully assessed and justified and deviations from current limits are possible.

The Heubach test involves passing air through a horizontal rotating drum containing a weighed amount of seed at a controlled flow rate over a fixed period of time. The dust generated is collected on a pre-weighed filter paper, and re-weighed to determine the amount. Again, the method is not designed to classify or reliably quantify the part of the seed treatment product that is not retained on the seeds.

Either CIPAC MT 194 or the Heubach tests are considered acceptable.

GLP – No

2.10d Storage of treated seed

There is no requirement to submit data to support stability/retention of the active substance on the stored seeds.

If no data are provided then the following statement should be added to the label:

Sowing treated seed that has been stored for prolonged periods (beyond the season of treatment) may adversely affect effectiveness and/or crop safety.

The fact that retention of the active substance is not a data requirement does not preclude companies from choosing to support a specific label claim concerning the period of time treated seed may be stored before sowing. In such instances, data should be generated with the storage period in any studies reflecting the length of time proposed on the label. To support carry over claims, data on seed loading after storage of the treated seeds must be provided. Efficacy data can be used as an alternative.

GLP – No

2.11 Other studies

Supplementary studies necessary for the classification of the plant protection product by hazard shall be carried out in accordance with Regulation (EC) No. 1272/2008.

Water soluble packaging

The packaging of preparations in water soluble bags/sachets may have an effect on the physical characteristics of the preparation and vice versa. Therefore, when seeking authorisation for such packaging, the relevant physical tests for that preparation type must be carried out in the presence of the soluble bag material in the same ratio(s) as that which will occur in the spray tank or other application equipment (see Note 1 underneath the tables of properties to be tested for each specific formulation for details of which properties need to be tested in the presence of aliquots of aqueous solution of bag material, in the correct ratio as discussed above).

In addition MT 176 must be carried out to determine the dissolution rate of the water soluble bag.

Acceptable limits :-	The time taken for the suspension to pass through the filter at the end of the test should not exceed 30 seconds.
Where a preparation is outside this limit then a practical sprayability test showing acceptable dissolution in a spray tank must be performed.	

GLP – No

When conducting storage stability tests with water soluble bags it is considered that storage under ambient temperature conditions is preferable to storage at elevated temperatures. There have been cases where the physical, chemical and technical properties of the preparation have been such that the bag material has deteriorated when stored and this may not have been observed under short term, elevated temperature testing. Consideration should also be given to the effects of low temperature storage on water soluble packaging.

Note that the water soluble bag is not considered part of the packaging, it is part of the formulation. Therefore storage stability in the outer commercial packaging should also be completed, for details see section 4.

4 Further information on the plant protection product

Effectiveness of cleaning procedures

Regulation (EU) No. 284/2013, paragraph 4.2 states that the effectiveness of the recommended tank cleaning procedures must be addressed. Data submitted must demonstrate that residues of the plant protection product do not remain in the spray tank after cleaning such that there is a risk to the operator or crops. The method used must be fully reported and justified; no standard agreed method is available at present.

Packaging (type materials, size, etc.), compatibility of the preparation with proposed packaging materials

General requirements

The packaging shall be designed in order to limit as much as possible exposure of operators and of the environment.

The packaging shall be designed and constructed so that its contents cannot escape (unless special safety devices have been prescribed); the materials constituting the packaging and fastenings must not be susceptible to attack by the contents, or liable to form harmful or dangerous compounds with the contents; the packaging and fastenings must be strong and solid throughout so as to ensure that they will not come apart and will safely withstand normal handling. Containers with fastening devices must be so designed that the container can be repeatedly refastened so that the contents cannot escape.

Full details of packaging must be included. This must include:

a) materials and manner of construction (e.g. extruded, welded, flexible, rigid);

b) barrier material;

c) details of closures and seals;

d) minimum and maximum container size and capacity including headspace (in case of containers for liquid formulations);

e) minimum wall thickness;

f) neck size;

g) details of any application device included with packaging;

h) whether the container is refillable/returnable;

i) outer packaging/sales pack;

j) any other features e.g. pressure release.

For multi-layer or co-extruded packaging each layer of the packaging should be described.

A statement must be provided that all packaging used complies with all relevant EU legislation on transportation and safe handling.

Following storage of the packaging any changes such as panelling, ballooning, condition of seals and seams and weight change must be reported in detail.

Extrapolation of packaging types

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Data in the form of an ambient temperature storage stability study are required to support each packaging type in which a plant protection product is authorised. The plant protection product must be stored in the worst case commercial packaging and the stability of this must be assessed. This should include observations on the appearance of the packaging and an assessment of the weight change on storage. This worst case packaging would be representative of the other commercial packaging types. The relevance of these data to the other proposed packaging types must be clearly outlined. Possible extrapolations are provided below but consideration should be given for specific cases.

Rigid containers for liquid preparations

For aqueous based formulation types e.g. SL, SC, LS, CS or FS, extrapolation between any plastic material types is acceptable. Extrapolation from plastic material to metals is not acceptable.

For organic solvent containing formulations e.g. EC, EW, SE or OD, extrapolation from HDPE to HDPE co-extruded with any of the following; EVOH, fluorinated HDPE and polyamide is acceptable. Extrapolation between plastic material types e.g. HDPE to PET is not acceptable.

Packaging used in shelf life study	**Acceptable extrapolations**
Water based formulations e.g. aqueous suspension concentrates, soluble concentrates	
Any, except metal	All rigid packaging types, apart from metal are supported with no further data
Organic Solvent based formulations e.g. emulsifiable concentrates	
HDPE	HDPE/EVOH, HDPE/F, HDPE/PA packs would all be supported without further data
HDPE/EVOH or HDPE/F or HDPE/PA	Data generated in one of these three packaging types will support authorisation in the other two types with acceptable seepage data in the required packaging. HDPE packs would be supported with acceptable seepage data*.

* Seepage data are only required to demonstrate that the required packaging is stable for the required shelf life (e.g. no leakage, no ballooning, no panelling of the packaging, no deformations) rather than a new shelf life study in which all physical, chemical and technical properties are investigated prior to and after storage. The weight change on storage should also be determined.

Containers for powders and granules

Extrapolation is possible between all container types. The material used must be waterproof or have a waterproof lining.

Bulk containers

Where it is proposed that a preparation is to be packaged in a bulk container (a container of size greater than 20 L), it is recognised that it is impractical to conduct

stability tests in the large containers. Therefore results from smaller volume containers (1 L upwards) may be used to extrapolate to the larger containers.

For liquid preparations full details must be provided on the means of mixing the preparation in the larger container before use (if required). Furthermore, if significant levels of sedimentation are observed after storage in the smaller container sizes, member states could request additional storage stability studies in larger volume packaging to address concerns with potential blockages when used in practice.

Multiple bags in a container

Where multiple water soluble bags are to be packaged in a single container, evidence is required that the integrity of the water soluble packaging is not affected either by the opening and re-sealing of the outer pack or by moisture entering through routine use. Therefore the following data are required:

a) Ambient testing – short term studies (only required if long term studies are unavailable)

Evidence must be submitted to demonstrate that the integrity and performance of the water soluble sachets/bags is unaffected by the repeated opening and resealing of the outer pack, under recommended conditions of storage and use. This may be achieved by storing a 'multi-bag' pack at ambient temperatures over a 6 month period and periodically removing the water soluble sachets/bags from the outer pack under normal handling and use conditions, until all the bags have been removed. On removing the water soluble sachets/bags, the integrity of each of the bags must be examined and the 'dissolution' characteristics of the water soluble sachets/bags tested (using MT 176).

b) Ambient testing long term studies

Ambient testing may be achieved by storing a 'multi-bag' pack at ambient temperatures over a 2 year period and periodically removing the water soluble sachets/bags from the outer pack under normal handling and use conditions, until all the bags have been removed. On removing the water soluble sachets/bags, the integrity of each of the bags must be examined and the 'dissolution' characteristics of the water soluble sachets/bags tested (using MT 176).

Trigger packs

For ready to use products supplied in a container with an integral trigger spray head the satisfactory operation of the trigger sprayer prior to and after storage should be addressed. This should include the spray pattern, the amount of spray delivered with each operation (or multiple operations) and observations on the trigger (build-up of crystallised material in the nozzles, nozzle blockage or leaks from the trigger head). Where the product is not applied in one single operation then the intermittent use of the sprayer during the storage interval should also be addressed by evaluation of the above parameters; the satisfactory operation of the sprayer following successive uses followed by storage of the product must reflect commercial practice.

If multiple types of trigger packs are requested with differing trigger mechanisms, then data generated to support each mechanism type will be required.

Re-usable/refillable packaging

If a container is re-useable it is the responsibility of the container owner when containers are returned to ensure that the package continues to be fit for purpose, and still complies with all relevant transport requirements.

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Appendix 1 Requirements for the technical characteristics of the plant protection product

The technical characteristics have been arranged according to the preparation type. Those properties which must be determined before and after storage are indicated. The properties required are in accordance with the Regulation (EC) No. 1107/2009 and the Manual on development and use of FAO and WHO specifications for pesticides.[9]

Where a test is not considered applicable to a particular preparation then this must be explained and justified.

Where information is not given on a specific formulation then a logical approach should be taken addressing the appropriate properties and using the relevant tests. This also applies to mixed formulation e.g. ZC, ZE and ZW.

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[9] Manual on development and use of FAO and WHO specifications for pesticides, 2016, 3rd revision of the 1st edition and any additional supplements.

1 Common Liquid preparations

1.1 Soluble concentrate (SL)

A clear to opalescent liquid to be applied as a solution of the active substance after dilution in water. The liquid may contain water-insoluble formulants.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations after storage should include whether any separation or crystallisation occurs.
2.2	Explosive properties	A 14, UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21, Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	
2.7	Low temperature stability	MT 39.3	The volume of solid and/or liquid which separates shall not be more than 0.3 mL.	
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.4	Dilution stability	MT 41.1	Data required before and after storage	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. Indicate if there is any seepage of solvent through the container walls or seal.

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1.2 Suspension concentrates (SC)

A stable suspension of active substance(s) with water as the fluid, intended for dilution with water before use.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations after storage should include whether any separation or sedimentation/claying occurs. Comment on re-dispersibility.
2.2	Explosive properties	A 14, UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	
2.7	Low temperature stability	MT 39.3	Suspensibility and wet sieve test should be determined after storage.	
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.3	Suspensibility	MT 184	Data required before and after storage	
2.8.3	Spontaneity of dispersion	MT 160	Data required before and after storage	
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	
2.8.7	Pourability	MT 148 or MT 148.1	Data required before and after storage	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. Indicate if there is any seepage of solvent through the container walls or seal.

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1.3 Capsule suspensions (CS)

A stable suspension of capsules in a fluid, normally intended for dilution with water before use.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	To include the determination of 'free' and 'encapsulated' active substance if required.* For controlled release capsules the release rate must be determined. Reference may be made to biological efficacy data.[10] Stability of the CS formulation in the spray tank determined at the in-use concentration should be determined. Consideration should also be given to the release rate of the active from the capsule once sprayed i.e. *in situ*.
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations after storage should include whether any separation or sedimentation/claying occurs. Comment on re-dispersibility.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	

[10] Refer to section 1.4.1 (page 6) for further details.

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Annex point	Property	Test Method	Storage stability requirements	Comments
2.7	Low temperature stability	MT 39.3	The low temperature stability testing should be carried out under a 'freeze/thaw' cycle to demonstrate that capsule integrity is not adversely affected. Unless otherwise agreed, the freeze/thaw stability test shall cycle the formulation between room temperature (e.g. 20 ± 2 °C) and -10 ± 2 °C on 18-hour-freeze/6-hour-melt cycles for a total of 4 cycles. See FAO manual note 12 for further details.	'Free' and 'encapsulated' active substance should be determined before and after storage.* Acidity/alkalinity/pH, pourability, spontaneity of dispersion, suspensibility and wet sieve test should be determined after storage.
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.3	Suspensibility	MT 184	Data required before and after storage	
2.8.3	Spontaneity of dispersion	MT 160	Data required before and after storage	
2.8.5.1	Particle size distribution	MT 187	Not required after storage	
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	
2.8.7	Pourability	MT 148 OR MT 148.1	Data required before and after storage	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. Indicate if there is any seepage of solvent through the container walls or seal.

* Determination of free active substance is usually required where encapsulation is intended to control the release or stability of the active substance to address volatility issues and the potential impact on non-target crops, or to decrease the risk to users from accidental exposure to the active substance.

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1.4 Emulsifiable concentrate (EC)

A liquid, homogeneous formulation to be applied as an emulsion after dilution in water.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations after storage should include whether any separation occurs. Comment on ease of re-homogenisation.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	
2.7	Low temperature stability	MT 39.3	The volume of solid and/or liquid which separates shall not be more than 0.3 mL. Emulsion stability should be determined after storage.	
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.6	Emulsifiability Re-emulsifiability Emulsion stability	MT 36.3	Data required before and after storage	Where no oil or cream separation after 2 hours, then the 24 hour test is not required.
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. Indicate if there is any seepage of solvent through the container walls or seal.

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1.5 Suspo-emulsions (SE)

A fluid, heterogeneous formulation consisting of a stable dispersion of active substances in the form of solid particles and fine globules in a continuous water phase.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations after storage should include whether any separation occurs. Comment on ease of re-homogenisation.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	
2.7	Low temperature stability	MT 39.3	Dispersion stability and wet sieve should be determined after storage.	
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.3	Dispersion stability	MT 180	Data required before and after storage	
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	
2.8.7	Pourability	MT 148 OR MT 148.1	Data required before and after storage	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. Indicate if there is any seepage of solvent through the container walls or seal.

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1.6 Dispersible concentrate (DC)

A liquid homogeneous formulation to be applied as a solid dispersion after dilution in water. (Note: there are some formulations which have characteristics intermediate between DC and EC).

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations after storage should include whether any separation or sedimentation/claying occurs. Comment on re-dispersibility.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	
2.7	Low temperature stability	MT 39.3	Dispersion stability should be determined after storage. The volume of solid and/or liquid which separates shall not be more than 0.3 mL.	
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.3	Dispersion stability	MT 180	Data required before and after storage	
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. Indicate if there is any seepage of solvent through the container walls or seal.

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1.7 Oil-in-water emulsions (EW)

EW - A fluid, heterogeneous formulation consisting of a solution of pesticide in an organic liquid dispersed as fine globules in a continuous water phase.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: physical state colour		Data required before and after storage	Observations after storage should include whether any separation occurs. Comment on ease of re-homogenisation.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	
2.7	Low temperature stability	MT 39.3	The volume of solid and/or liquid which separates shall not be more than 0.3 mL. Emulsion stability should be determined after storage.	
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.6	Emulsifiability Re-emulsifiability Emulsion stability	MT 36.3	Data required before and after storage	Where no oil or cream separation after 2 hours, then the 24 hour test is not required.
2.8.7	Pourability	MT 148 or MT 148.1	Data required before and after storage	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. Indicate if there is any seepage of solvent through the container walls or seal.

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1.8 Micro emulsions (ME)

ME - A clear to opalescent, oil and water containing liquid, to be applied directly or after dilution in water, when it may form a diluted micro-emulsion or a conventional emulsion.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: physical state colour		Data required before and after storage	Observations after storage should include whether any separation occurs. Comment on ease of re-homogenisation.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	
2.7	Low temperature stability	MT 39.3	The volume of solid and/or liquid which separates shall not be more than 0.3 mL. In certain circumstances phase separation may occur. The formulation is deemed acceptable if the recovery to a single phase is as rapid as the thermal equilibrium with ambient or use temperatures (see FAO manual, note 9). Emulsion stability should be determined after storage.	
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.6	Emulsifiability Re-emulsifiability Emulsion stability	MT 36.3	Data required before and after storage	Where no oil or cream separation after 2 hours, then the 24 hour test is not required.
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. Indicate if there is any seepage of solvent through the container walls or seal.

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1.9 Oil Dispersion (OD)

A stable suspension of active substance(s) in a water-immiscible fluid, which may contain other dissolved active substance(s), intended for dilution with water before use.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations after storage should include whether any separation occurs. Comment on ease of re-homogenisation.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	
2.7	Low temperature stability	MT 39.3	Dispersion stability and wet sieve should be determined after storage.	
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.3	Dispersion stability	MT 180	Data required before and after storage	
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	
2.8.7	Pourability	MT 148 or MT 148.1	Data required before and after storage	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. Indicate if there is any separation or seepage through the container walls or seal.

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1.10 Ultra low volume preparations (UL)

Ultra low volume preparations are generally designed for application through special equipment. Hence the physical characteristics of the preparation are also dependent on the type of equipment recommended.

In addition to the characteristics described below, the potential for loss of droplet mass is critical for UL preparations as this can affect spray drift during application. For this reason determination of droplet size is required both before and after storage. In determining the stability of the preparation, either the physical characteristics such as viscosity or droplet size may be determined or evidence must be provided that the preparation may be satisfactorily applied through the recommended application equipment.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	
2.7	Low temperature stability	MT 39.3	The volume of solid and/or liquid which separates shall not be more than 0.3 mL.	
2.8.5.1	Wet sieve test	MT 185	Data required before and after storage	Only applicable to water dispersible products.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. Indicate if there is any separation or seepage through the container walls or seal.
2.11	Droplet size	ASTM E1260 or another appropriate validated method	Data required before and after storage	

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1.11 Oil miscible liquids (OL)

A liquid, homogeneous formulation to be applied as a homogeneous liquid after dilution in an organic liquid.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	
2.7	Low temperature stability	MT 39.3	The volume of solid and/or liquid which separates shall not be more than 0.3 mL.	
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. Indicate if there is any separation or seepage through the container walls or seal.
2.11	Miscibility with hydrocarbon oil	MT 23	Data required before and after storage	The formulation shall be miscible with the appropriate hydrocarbon oil. Use the highest and lowest dilutions as recommended on the product label.

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1.12 Mixed formulations of CS and SC (ZC)

A stable suspension of capsules and active substance(s) in fluid, normally intended for dilution with water before use.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	To include the determination of 'free' and 'encapsulated' active substance if required.* For controlled release capsules the release rate must be determined. Reference may be made to biological efficacy data.[11] Stability of the CS formulation in the spray tank determined at the in-use concentration should be determined. Consideration should also be given to the release rate of the active from the capsule once sprayed i.e. *in situ*.
2.1	Appearance: physical state colour		Data required before and after storage	Observations after storage should include whether any separation or sedimentation/claying occurs. Comment on re-dispersibility.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	

[11] Refer to section 1.4.1 (page 6) for further details.

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Annex point	Property	Test Method	Storage stability requirements	Comments
2.7	Low temperature stability	MT 39.3	The low temperature stability testing should be carried out under a 'freeze/thaw' cycle to demonstrate that capsule integrity is not adversely affected. Unless otherwise agreed, the freeze/thaw stability test shall cycle the formulation between room temperature (e.g. 20 ± 2 °C) and -10 ± 2 °C on 18-hour-freeze/6-hour-melt cycles for a total of 4 cycles. See FAO manual note 12 for further details.	'Free' and 'encapsulated' active substance should be determined before and after storage.* Acidity/alkalinity/pH, pourability, spontaneity of dispersion, suspensibility and wet sieve test should be determined after storage.
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.3	Suspensibility	MT 184	Data required before and after storage	
2.8.3	Spontaneity of dispersion	MT 160	Data required before and after storage	
2.8.5.1	Particle size distribution	MT 187	Not required after storage	
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	
2.8.7	Pourability	MT 148 or MT 148.1	Data required before and after storage	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. Indicate if there is any separation or seepage through the container walls or seal.

* Determination of free active substance is usually required where encapsulation is intended to control the release or stability of the active substance to address volatility issues and the potential impact on non-target crops, or to decrease the risk to users from accidental exposure to the active substance.

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1.13 Mixed formulations of CS and EW (ZW)

A fluid, heterogeneous formulation consisting of a stable dispersion of active substance(s) in the form of capsules and fine globules in a continuous water phase, normally intended for dilution with water before use.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	To include the determination of 'free' and 'encapsulated' active substance if required.* For controlled release capsules the release rate must be determined. Reference may be made to biological efficacy data.[12] Stability of the CS formulation in the spray tank determined at the in-use concentration should be determined. Consideration should also be given to the release rate of the active from the capsule once sprayed i.e. *in situ*.
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations after storage should include whether any separation or sedimentation/ claying occurs. Comment on re-dispersibility.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	

[12] Refer to section 1.4.1 (page 6) for further details.

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Annex point	Property	Test Method	Storage stability requirements	Comments
2.7	Low temperature stability	MT 39.3	The low temperature stability testing should be carried out under a 'freeze/thaw' cycle to demonstrate that capsule integrity is not adversely affected. Unless otherwise agreed, the freeze/thaw stability test shall cycle the formulation between room temperature (e.g. 20 ± 2 °C) and -10 ± 2 °C on 18-hour-freeze/6-hour-melt cycles for a total of 4 cycles. See FAO manual note 11 for further details.	'Free' and 'encapsulated' active substance should be determined before and after storage.* Acidity/alkalinity/pH, pourability, dispersion stability and wet sieve test should be determined after storage.
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.3	Dispersion stability	MT 180	Data required before and after storage	
2.8.5.1	Particle size distribution	MT 187	Not required after storage	
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	
2.8.7	Pourability	MT 148 or MT 148.1	Data required before and after storage	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. Indicate if there is any separation or seepage through the container walls or seal.

* Determination of free active substance is usually required where encapsulation is intended to control the release or stability of the active substance to address volatility issues and the potential impact on non-target crops, or to decrease the risk to users from accidental exposure to the active substance.

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1.14 Mixed formulations of CS and SE (ZE)

A fluid, heterogeneous formulation consisting of a stable dispersion of active substance(s) in the form of capsules, solid particles, and fine globules in a continuous water phase, normally intended for dilution with water before use.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	To include the determination of 'free' and 'encapsulated' active substance if required.* For controlled release capsules the release rate must be determined. Reference may be made to biological efficacy data.[13] Stability of the CS formulation in the spray tank determined at the in-use concentration should be determined. Consideration should also be given to the release rate of the active from the capsule once sprayed i.e. *in situ*.
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations after storage should include whether any separation or sedimentation/ claying occurs. Comment on re-dispersibility.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	

[13] Refer to section 1.4.1 (page 6) for further details.

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Annex point	Property	Test Method	Storage stability requirements	Comments
2.7	Low temperature stability	MT 39.3	The low temperature stability testing should be carried out under a 'freeze/thaw' cycle to demonstrate that capsule integrity is not adversely affected. Unless otherwise agreed, the freeze/thaw stability test shall cycle the formulation between room temperature (e.g. 20 ± 2 °C) and -10 ± 2 °C on 18-hour-freeze/6-hour-melt cycles for a total of 4 cycles. See FAO manual, note 11 for further details.	'Free' and 'encapsulated' active substance should be determined before and after storage.* Acidity/alkalinity/pH, pourability, dispersion stability and wet sieve test should be determined after storage.
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.3	Dispersion stability	MT 180	Data required before and after storage	
2.8.5.1	Particle size distribution	MT 187	Not required after storage	
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	
2.8.7	Pourability	MT 148 or MT 148.1	Data required before and after storage	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. Indicate if there is any separation or seepage through the container walls or seal.

* Determination of free active substance is usually required where encapsulation is intended to control the release or stability of the active substance to address volatility issues and the potential impact on non-target crops, or to decrease the risk to users from accidental exposure to the active substance.

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2 Common Solid preparations

2.1 Granules (GR)

A free-flowing solid formulation of a defined granule size range ready for use.

The guidelines for granules are intended only to cover those preparations that are designed to be applied in dry form by mechanical means.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations of granule integrity are required before and after storage.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A10, A16 Or Test N.1 Test N.4	Not required after storage	
2.6	Bulk density	MT 186	Not required after storage	
2.8.5.1	Dry sieve test	MT 170	Data required before and after storage	
2.8.5.2	Dust content	MT 171.1	Data required before and after storage	Products should be 'nearly dust free' (category 1) or 'essentially non dusty' (category 2). For products that fall outside these categories the implications for the potential risk to operators, residents and bystanders must be addressed.
2.8.5.3	Attrition	MT 178	Data required before and after storage	
2.8.7	Flowability	MT 172.1	Determined after accelerated storage under pressure in accordance with the method.	
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. There should be no loss of granule integrity or caking on storage.

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2.2 Water dispersible granules (WG) and water dispersible granules in sealed water soluble bags (WG-SB) (note 1)

A formulation consisting of granules to be applied after disintegration and dispersion in water.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations of granule integrity are required before and after storage.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A10, A16 Test N.1 Test N.4	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.6	Bulk density	MT 186	Not required after storage	
2.8.1	Wettability	MT 53.3	Data required before and after storage	
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.3	Suspensibility	MT 184	Data required before and after storage	
2.8.3	Spontaneity of dispersion	MT 174	Data required before and after storage	
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	
2.8.5.1	Dry sieve test	MT 170	Data required before and after storage	
2.8.5.2	Dust content	MT 171.1	Data required before and after storage	Products should be 'nearly dust free' (category 1) or 'essentially non dusty' (category 2). For products that fall outside these categories the implications for the potential risk to operators, residents and bystanders must be addressed.
2.8.5.3	Attrition	MT 178.2	Data required before and after storage	
2.8.7	Flowability	MT 172.1	Determined after accelerated storage under pressure in accordance with the method.	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. There should be no loss of

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				granule integrity or caking on storage.
2.11	Dissolution of the bag	MT 176	Data required before and after storage	Only required for WG-SB.

Note 1: For a water soluble bag, lay the bag on a bench and carefully open one side of the bag with a cutter, taking care not to damage the seals. Transfer the contents of the bag into a suitable flask. This material shall be used to carry out the tests for:

- Active substance content;
- Explosive properties;
- Oxidising properties;
- Flammability and self-heating;
- pH, acidity/alkalinity;
- Bulk density;
- Wettability;
- Persistent foam;
- Suspensibility;
- Spontaneity of dispersion;
- Wet sieve;
- Dry sieve;
- Dust content;
- Attrition;
- Flowability;
- Dissolution of the bag.

The bag is then opened on three sides, completely cleaned from adhering powder by brushing or suction and weighed to the nearest 0.01 g. It shall be used to carry out the dissolution test. Aliquots of an aqueous solution of the bag material shall be used in the suspensibility and persistent foam tests. In the case of delay of the above tests, the bag shall be stored in a watertight container (glass bottle or equivalent) to avoid any change in its properties.

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2.3 Water soluble granules (SG) and water soluble granules in sealed water soluble bags (SG-SB) (note 1)

A formulation consisting of granules to be applied as a true solution of the active substance after dissolution in water, but which may contain insoluble inert ingredients.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations of granule integrity are required before and after storage.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A10, A16 Test N.1 Test N.4	Not required after storage	
2.4	pH Acidity/ alkalinity(if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.6	Bulk density	MT 186	Not required after storage	
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.4	Degree of dissolution and dilution stability	MT 179.1	Data required before and after storage	
2.8.5.1	Dry sieve test	MT 170	Data required before and after storage	
2.8.5.2	Dust content	MT 171.1	Data required before and after storage	Products should be 'nearly dust free' (category 1) or 'essentially non dusty' (category 2). For products that fall outside these categories the implications for the potential risk to operators, residents and bystanders must be addressed.
2.8.5.3	Attrition	MT 178.2	Data required before and after storage	
2.8.7	Flowability	MT 172.1	Determined after accelerated storage under pressure in accordance with the method.	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. There should be no loss of granule integrity or caking on storage.
2.11	Dissolution of the bag	MT 176	Data required before and after storage	Only required for SG-SB.

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Note 1: For a water soluble bag, lay the bag on a bench and carefully open one side of the bag with a cutter, taking care not to damage the seals. Transfer the contents of the bag into a suitable flask. This material shall be used to carry out the tests for:

- Active substance content;
- Explosive properties;
- Oxidising properties;
- Flammability and self-heating;
- pH, acidity/alkalinity;
- Bulk density;
- Persistent foam;
- Degree of dissolution and dilution stability;
- Dry sieve;
- Dust content;
- Attrition;
- Flowability;
- Dissolution of the bag;

The bag is then opened on three sides, completely cleaned from adhering powder by brushing or suction and weighed to the nearest 0.01 g. It shall be used to carry out the dissolution test. Aliquots of an aqueous solution of the bag material shall be used in the dilution stability and persistent foam tests.

In the case of delay of the above tests, the bag shall be stored in a watertight container (glass bottle or equivalent) to avoid any change in its properties.

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2.4 Emulsifiable granules (EG) and emulsifiable granules in sealed water soluble bags (note 1)

A granular formulation, which may contain water-insoluble formulants, to be applied as an oil-in-water emulsion of the active substance(s) after disintegration in water.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations of granule integrity are required before and after storage.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A10, A16 Test N.1 Test N.4	Not required after storage	
2.4	pH Acidity/ alkalinity(if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.6	Bulk density	MT 186	Not required after storage	
2.8.1	Wettability	MT 53.3	Data required before and after storage	
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.4	Dispersion stability	MT 180	Data required before and after storage	
2.8.5.1	Wet sieve	MT185	Data required before and after storage	
2.8.5.1	Dry sieve test	MT 170	Data required before and after storage	
2.8.5.2	Dust content	MT 171.1	Data required before and after storage	Products should be 'nearly dust free' (category 1) or 'essentially non dusty' (category 2). For products that fall outside these categories the implications for the potential risk to operators, residents and bystanders must be addressed.
2.8.5.3	Attrition	MT 178.2	Data required before and after storage	
2.8.7	Flowability	MT 172.1	Determined after accelerated storage under pressure in accordance with the method.	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. There should be no loss of granule integrity or caking

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Annex point	Property	Test Method	Storage stability requirements	Comments
				on storage.
2.11	Dissolution of the bag	MT 176	Data required before and after storage	Only required for emulsifiable granules in sealed water soluble bags.

Note 1: For a water soluble bag, lay the bag on a bench and carefully open one side of the bag with a cutter, taking care not to damage the seals. Transfer the contents of the bag into a suitable flask. This material shall be used to carry out the tests for:

- Active substance content;
- Explosive properties;
- Oxidising properties;
- Flammability and self-heating;
- pH, acidity/alkalinity;
- Bulk density;
- Wettability;
- Persistent foam;
- Dispersion stability;
- Wet sieve;
- Dry sieve;
- Dust content;
- Attrition;
- Flowability;
- Dissolution of the bag.

The bag is then opened on three sides, completely cleaned from adhering powder by brushing or suction and weighed to the nearest 0.01 g. It shall be used to carry out the dissolution test. Aliquots of an aqueous solution of the bag material shall be used in the dispersion stability and persistent foam tests.

In the case of delay of the above tests, the bag shall be stored in a watertight container (glass bottle or equivalent) to avoid any change in its properties.

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2.5 Wettable powders (WP) and wettable powders in sealed water soluble bags (WP-SB) (note 1)

A powder formulation to be applied as a suspension after dispersion in water.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A10, A16 Test N.1 Test N.4	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.6	Bulk density	MT 186	Not required after storage	
2.8.1	Wettability	MT 53.3	Data required before and after storage	
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.3	Suspensibility	MT 184	Data required before and after storage	
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observations of pack stability including weight change and comment whether any caking or compaction has occurred on storage.
2.11	Dissolution of the bag	MT 176	Data required before and after storage	Only required for WP-SB.

Note 1: For a water soluble bag, lay the bag on a bench and carefully open one side of the bag with a cutter, taking care not to damage the seals. Transfer the contents of the bag into a suitable flask. This material shall be used to carry out the tests for:

- Active substance content;
- Explosive properties;
- Oxidising properties;
- Flammability and self-heating;
- pH, acidity/alkalinity;
- Bulk density;
- Wettability;
- Persistent foam;

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- Suspensibility;
- Wet sieve;
- Dissolution of the bag.

The bag is then opened on three sides, completely cleaned from adhering powder by brushing or suction and weighed to the nearest 0.01 g. It shall be used to carry out the dissolution test. Aliquots of an aqueous solution of the bag material shall be used in the suspensibility and persistent foam tests.

In the case of delay of the above tests, the bag shall be stored in a watertight container (glass bottle or equivalent) to avoid any change in its properties.

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2.6 Water soluble powders (SP) and water soluble powders in water soluble bags (note 1)

A powder formulation to be applied as a true solution of the active substance after dissolution in water, but which may contain insoluble inert ingredients.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	appropriate validated method	Data required before and after storage	
2.1	Appearance: physical state colour		Data required before and after storage	
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A10, A16 Test N.1 Test N.4	Not required after storage	
2.4	pH acidity/ alkalinity(if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.6	Bulk density	MT 186	Not required after storage	
2.8.1	Wettability	MT 53.3	Data required before and after storage	
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.4	Degree of dissolution and dilution stability	MT 179.1	Data required before and after storage	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observations of pack stability including weight change and comment whether any caking or compaction has occurred on storage.
2.11	Dissolution of the bag	MT 176	Data required before and after storage	Only required for water soluble powders in water soluble bags.

Note 1: For a water soluble bag, lay the bag on a bench and carefully open one side of the bag with a cutter, taking care not to damage the seals. Transfer the contents of the bag into a suitable flask. This material shall be used to carry out the tests for:

- Active substance content;
- Explosive properties;
- Oxidising properties;
- Flammability and self-heating;
- pH, acidity/alkalinity;
- Bulk density;
- Wettability;

- Persistent foam;
- Degree of dissolution and dilution stability;
- Dissolution of the bag.

The bag is then opened on three sides, completely cleaned from adhering powder by brushing or suction and weighed to the nearest 0.01 g. It shall be used to carry out the dissolution test. Aliquots of an aqueous solution of the bag material shall be used in the dilution stability and persistent foam tests.

In the case of delay of the above tests, the bag shall be stored in a watertight container (glass bottle or equivalent) to avoid any change in its properties.

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2.7 Dustable powders (DP)

A free-flowing powder suitable for dusting.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A10, A16 Test N.1 Test N.4	Not required after storage	
2.6	Bulk density	MT 186	Not required after storage	
2.8.5.1	Particle size distribution	MT 187	data required before and after storage	
2.8.5.1	Dry sieve test	MT 170	Data required before and after storage	
2.8.7	Dustability	MT 34 or an appropriate method	Data required before and after storage	Evidence that the preparation may be satisfactorily applied through the equipment or from container specified.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observations of pack stability including weight change and comment whether any caking or compaction has occurred on storage.

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2.8 Emulsifiable powders (EP) and emulsifiable powders and water soluble bags (note 1)

A powder formulation, which may contain water-insoluble formulants, to be applied as an oil-in-water emulsion of the active substance(s) after dispersion in water.
Water emulsifiable powders may contain one or more active substance(s), either solubilized or diluted in suitable organic solvent(s) which is (are) absorbed in a water soluble polymer powder or other type of soluble or insoluble powder.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A10, A16 Test N.1 Test N.4	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.6	Bulk density	MT 186	Not required after storage	
2.8.1	Wettability	MT 53.3	Data required before and after storage	
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.3	Dispersion stability	MT 180	Data required before and after storage	
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observations of pack stability including weight change and comment whether any caking or compaction has occurred on storage.
2.11	Dissolution of the bag	MT 176	Data required before and after storage	Only required for water soluble powders in water soluble bags.

Note 1: For a water soluble bag, lay the bag on a bench and carefully open one side of the bag with a cutter, taking care not to damage the seals. Transfer the contents of the bag into a suitable flask. This material shall be used to carry out the tests for:

- Active substance content;
- Explosive properties;
- Oxidising properties;

- Flammability and self-heating;
- pH, acidity/alkalinity;
- Bulk density;
- Wettability;
- Persistent foam;
- Dispersion stability;
- Wet sieve;
- Dissolution of the bag.

The bag is then opened on three sides, completely cleaned from adhering powder by brushing or suction and weighed to the nearest 0.01 g. It shall be used to carry out the dissolution test. Aliquots of an aqueous solution of the bag material shall be used in the dispersion stability and persistent foam tests.

In the case of delay of the above tests, the bag shall be stored in a watertight container (glass bottle or equivalent) to avoid any change in its properties.

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2.9 Tablets for direct application (DT)

Tablets for direct application (DT) are intended for application directly in the field and/or bodies of water without preparation of a spraying solution or dispersion.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	Tablet dose uniformity should also be determined if required.
2.1	Appearance: Physical state Colour		Data required before and after storage	
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A10, A16 Test N.1 Test N.4	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	Only required when application is to bodies of water.
2.8.5.3	Attrition	MT 178 or MT 193	Data required before and after storage	Only required for tablets packaged in bulk.
2.8.5.4	Hardness† and integrity	Visual observation (integrity)	Data required before and after storage	
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change.

† As of April 2018, there is no specific method for hardness, a CIPAC method is under consideration.

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2.10 Water dispersible tablets (WT)

Water dispersible tablets (WT) are intended for application after disintegration and dispersion in water by conventional spraying equipment.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: physical state colour		Data required before and after storage	
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A 10, A 16 Test N.1 Test N.4	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	Not applicable to effervescent tablets.
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.3	Suspensibility	MT 184	Data required before and after storage	
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	
2.8.5.3	Attrition	MT 178 or MT 193	Data required before and after storage	Only required for tablets packaged in bulk.
2.8.5.4	Hardness† and integrity	Visual observation (integrity)	Data required before and after storage	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change.
2.11	Disintegration of tablets	MT 197	Data required before and after storage	The data should demonstrate the tablet disintegrates rapidly on addition to water and that the formulation is readily dispersed.

† As of April 2018 there is no specific method for hardness, a CIPAC method is under consideration.

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2.11 Water soluble tablets (ST)

Water soluble tablets (ST) are intended for application after dissolution in water by conventional spraying equipment. STs contain an active substance which is totally soluble in water at use rate concentrations.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	Tablet dose uniformity should also be determined if required.
2.1	Appearance: Physical state Colour		Data required before and after storage	
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A10, A16 Test N.1 Test N.4	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191	Data required before and after storage	Not applicable to effervescent tablets.
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.4	Degree of dissolution and dilution stability	MT 196	Data required before and after storage	
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	
2.8.5.3	Attrition	MT 178 or MT 193	Data required before and after storage	Only required for tablets packaged in bulk.
2.8.5.4	Hardness† and integrity	Visual observation (integrity)	Data required before and after storage	The data should demonstrate the mechanical robustness of the tablet and the stability in transport and use.
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change.
2.11	Disintegration of tablets	MT 197	Data required before and after storage	The data should demonstrate the tablet disintegrates rapidly on addition to water and that the formulation is readily dissolved.

† As of April 2018, there is no specific method for hardness, a CIPAC method is under consideration.

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3 Seed treatments

Seed treatment formulations in general are expected to contain a dye or pigment that permanently colours the seed after treatment (red is recommended). For special purposes however, the dye/pigment can be added at a later stage. In some countries, there may be a legal requirement that a specific colour shall be used. The same colour must not be used for denaturing seeds intended for use as livestock feeding stuffs.

3.1 Flowable concentrate for seed treatment (FS)

A stable suspension for application to the seed, either directly or after dilution.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations after storage should include whether any separation or sedimentation/ claying occurs. Comment on re-dispersibility.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	
2.7	Low temperature stability	MT 39.3	Wet sieve should be determined after storage.	
2.8.2	Persistent foam	MT 47.3	Not required after storage	Not required if the product is not to be diluted before use.
2.8.3	Suspensibility	MT 184	Data required before and after storage	If the methods are not applicable to in use concentrations, evidence is required that there is no unacceptable phase separation on application after dilution with water. Evidence is required the preparation is homogeneous if it is not to be diluted before use.
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	

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Annex point	Property	Test Method	Storage stability requirements	Comments
2.8.7	Pourability	MT 148.1	Data required before and after storage	If applicable to the container and use instructions.
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.10	Adherence to seeds	MT 194	Data required before and after storage	
2.10	Seed loading	appropriate validated method		
2.10	Distribution to seeds	MT 175		
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change. Indicate if there is any separation or seepage through the container walls or seal.

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3.2 Solutions for seed treatments (LS)

A clear to opalescent liquid to be applied to the seed either directly or as a solution of the active substance after dilution in water. The liquid may contain water-insoluble formulants.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations after storage should include whether any separation or crystallisation occurs.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	
2.7	Low temperature stability	MT 39.3	The volume of solid and/or liquid which separates shall not be more than 0.3 mL.	
2.8.2	Persistent foam	MT 47.3	Not required after storage	Not required if the product is not to be diluted before use.
2.8.4	Dilution stability	MT 41.1	Data required before and after storage	The preparation should form a clear or opalescent solution, free from more than a trace of sediment and visible solid particles after dilution with water. Any visible sediment or particles produced shall pass through a 75 µm test sieve. Not required if the product is not to be diluted before use.
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if product is to be applied in a mixture with other PPPs.
2.10	Adherence to seeds	MT 194	Data required before and after storage	
2.10	Seed loading	Appropriate validated method		
2.10	Distribution to seeds	MT 175		
2.7	Stability of packaging and		Data required before and	Observation of pack

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	packaging/preparation interactions		after storage	stability including weight change. Indicate if there is any separation or seepage through the container walls or seal.

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3.3 Emulsions for seed treatments (ES)

A stable emulsion for application to the seed either directly or after dilution.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations after storage should include whether any separation occurs. Comment on ease of re-homogenisation.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	
2.7	Low temperature stability	MT 39.3	No separation of particulate or oily matter shall be visible after gentle agitation.	
2.8.2	Persistent foam	MT 47.3	Not required after storage	Not required if the product is not to be diluted before use.
2.8.6	Emulsifiability Re-emulsifiability Emulsion stability	MT 36.3	Data required before and after storage	If the methods are not applicable to in use concentrations, evidence required that there is no unacceptable phase separation on application after dilution with water. Evidence is required the preparation is homogeneous if it is not to be diluted before use.
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if product is to be applied in a mixture with other PPPs.
2.10	Adherence to seeds	MT 194	Data required before and after storage	
2.10	Seed loading	Appropriate validated method		
2.10	Distribution to seeds	MT 175		
2.7	Stability of packaging and packaging/preparation		Data required before and after storage	Observation of pack stability including weight

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	interactions			change. Indicate if there is any seepage of solvent through the container walls or seal.

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3.4 Powders for dry seed treatments (DS)

A powder for application in the dry state directly to the seed.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A10, A16 Test N.1 Test N.4	Not required after storage	
2.6	Bulk density	MT 186	Not required after storage	
2.8.5.1	Dry sieve test	MT 170	Data required before and after storage	If results show > 1 % w/w dust then the particle size of the dust generated shall be determined in accordance with MT 187.
2.8.7	Dustability	MT 34 or an appropriate method	Data required before and after storage	Evidence that the preparation may be satisfactorily applied through the equipment or from container specified.
2.10	Adherence to seeds	MT 194	Data required before and after storage	
2.10	Seed loading	Appropriate validated method		
2.10	Distribution to seeds	Appropriate validated method		
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observations of pack stability including weight change and comment whether any caking or compaction has occurred on storage.

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3.5 Water dispersible powders for slurry seed treatment (WS)

A powder to be dispersed at high concentration in water before application as a slurry to the seed.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A10, A16 Test N.1 Test N.4	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.6	Bulk density	MT 186	Not required after storage	
2.8.1	Wettability	MT 53.3	Data required before and after storage	
2.8.2	Persistent foam	MT 47.3	Not required after storage	May not be applicable if the product is applied at very high concentration as a slurry.
2.8.3	Suspensibility	MT 184	Data required before and after storage	If the methods are not applicable to in use concentrations, evidence is required that the dispersion is homogeneous.
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if product is to be applied in a mixture with other PPPs.
2.10	Adherence to seeds	MT 194	Data required before and after storage	
2.10	Seed loading	Appropriate validated method		
2.10	Distribution to seeds	Appropriate validated method		
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observations of pack stability including weight change and comment whether any caking or compaction has occurred on storage.

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3.6 Water soluble powders for seed treatment (SS)

A powder formulation to be applied to the seed as a true solution of the active substance in water.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations of granule integrity are required before and after storage.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A10, A16 Test N.1 Test N.4	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.6	Bulk density	MT 186	Not required after storage	
2.8.1	Wettability	MT 53.3	Data required before and after storage	
2.8.2	Persistent foam	MT 47.3	Not required after storage	
2.8.4	Degree of dissolution	MT 179.1	Data required before and after storage	
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.10	Adherence to seeds	MT 194	Data required before and after storage	
2.10	Seed loading	Appropriate validated method		
2.10	Distribution to seeds	MT 175		
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observations of pack stability including weight change and comment whether any caking or compaction has occurred on storage.

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4 Miscellaneous

4.1 Smoke generator (FU)

A combustible formulation, generally solid, which upon ignition releases the active substance(s) in the form of smoke.

Evidence is required that the preparation generates a smoke when used according to label recommendations.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	Evidence is also required that active substance is stable at the temperatures likely to occur in smoking.[14]
2.1	Appearance: Physical state Colour		Data required before and after storage	
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A10, A15, A16 Test N.1 Test N.4	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.6	Bulk density	MT 186	Not required after storage	
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability and integrity including weight change on storage.
2.11	Burning time[15]	No standard method	Data required before and after storage	Evidence is required that the preparation may be satisfactorily applied as a smoke.
2.11	Evidence of combustibility[16]	No standard method	Data required before and after storage	The quantity of material remaining after combustion (including unvolatilised active substance) should be

[14] This is required to confirm that the smoke delivers the required active substance concentration as stated on the product label.

[15] The duration and burning rate of a smoke generator should be specified to establish how long it takes before the preparation stops generating smoke. Data are required, based on a representative in-use situation, to show the burning rate and duration comply with the specified rates on the product label. Where relevant the data must support intermittent use of the product.

[16] Evidence of combustibility (completeness of burning) can be determined by weighing the preparation before and after use. It should be demonstrated that by far the largest part of the active substance was volatised in the smoke composition. This also requires determination of the concentration of active substance in the residue.

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				determined.
2.11	Composition of smoke[17]	No standard method	Data required before and after storage	The smoke composition must be analysed for the concentration of the active substance and decomposition products, if any, to guarantee that the produced smoke does indeed contain the active substance and no decomposition products.

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[17] If, based on theoretical considerations, e.g. based on the endpoints provided for the active substance (degradation/combustion products after decomposition), or the heat generated during the generation of smoke is well below the decomposition temperature of the active substance and/or the absence of halogens or other compounds which may generate toxic fumes, a test may be waived.

4.3 Fogging concentrates, hot fogging (HN) cold fogging (KN)

HN - A formulation suitable for application by hot fogging equipment, either directly or after dilution.
KN - A formulation suitable for application by cold fogging equipment, either directly or after dilution.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	Evidence is also required that the active substance is stable at the temperatures likely to occur in fogging machinery.
2.1	Appearance: Physical state Colour		Data required before and after storage	
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17, A21, Test O.1, O.2 or O.3	Not required after storage	
2.3	Flammability and self-heating	A9, A10, A15, A16 Test N.1 ortest N.4	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3, MT 191 orMT 31	Data required before and after storage	
2.5	Viscosity	OECD 114 MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	Only required for liquid products.
2.6	Relative density Bulk density	A 3 or OECD 109 MT 186	Not required after storage	
2.7	Low temperature stability	MT 39.3		Only required for liquid products.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change and comment whether any pack deterioration on storage.

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4.4 Gels (GD, GL, GW)

GD – Gel for direct application; a gel-like preparation to be applied undiluted.
GL – Emulsifiable gel; a gelatinized formulation to be applied as an emulsion in water.
GW – Water soluble gel; a gelatinized formulation to be applied as an aqueous solution.
Gels are jelly-like colloidal systems of complex physical chemistry. Gels may either be dispersed in water before use or formulated as 'ready to use' preparations. The data required on the technical characteristics of the preparation will be dependent on its mode of use e.g. if the preparation is a water soluble gel then data on dilution stability will be required or for an emulsifiable gel emulsification will be required.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 21 Test O.2	Not required after storage	
2.3	Flammability and self-heating	A9, A15	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.5	Viscosity	OECD 114, MT 192 or MT 22	Not required after storage	
2.5	Surface tension	A 5 or OECD 115	Not required after storage	
2.6	Relative density	A 3 or OECD 109	Not required after storage	It may be more appropriate to treat as a solid depending on viscosity.
2.7	Low temperature stability	MT 39.3	The following properties should be determined as relevant: The volume of solid and/or liquid which separates shall not be more than 0.3 mL. Emulsion stability should be determined after storage. Suspensibility and wet sieve test should be determined after storage.	
2.8.2	Persistent foam	MT 47.3	Not required after storage	Required if the preparation is to be dissolved/dispersed in water.
2.8.3	Suspensibility	MT 184	Data required before and after storage	Only required if the preparation is to be dispersed in water.
2.8.3	Spontaneity	MT 160	Data required before and after storage	
2.8.4	Dilution stability	MT 179.1	Data required before and after storage	Only required if the preparation is to be dissolved in water.
2.8.5.1	Wet sieve	MT 185	Data required before and after storage	Only required if the preparation is to be

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				dispersed in water.
2.8.6	Emulsifiability Re-emulsifiability Emulsion stability	MT 36.3	Data required before and after storage	Only required if the preparation is to be emulsified in water.
2.9	Physical and chemical compatibility	ASTM E1518-05	Not required after storage	Required if tank mixes are recommended on the label.
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observations of pack stability including weight change. Indicate if there has been seepage/migration of the active substance.

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4.5 Baits:- Bait concentrate (CB) and ready-to-use bait (RB)

These requirements should be read in conjunction for those describing the efficacy of the preparation as there are some areas where data for the biological efficacy of the preparation may be used to support the preparation chemistry and storage stability requirements. For preparations with the same bait base which differ only in active substance content, there may be scope to extrapolate some data between different preparations.

For a bait concentrate that is required to be diluted before use, the appropriate dilution properties should be determined (e.g. dilution stability, dispersion properties, emulsifiability, etc.). Please refer to previous tables for details on individual properties that are required depending on the nature of the dilution.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	Evidence must be provided that the bait retains the physical state including observations of compaction on storage and there is no obvious bio-degradation e.g. microbial growth. For all baits it must be demonstrated that the product can be satisfactorily applied according to the recommendations on the label.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A10, A12, A16 Test N.1 Test N.4	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.6	Relative density Bulk density	A 3 or OECD 109 MT 186	Not required after storage	
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change.
2.11	Retention of palatability		After storage	Evidence of retention of biological efficacy may be acceptable but consideration must be given to the number of animals required in testing.

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4.6 Plant rodlet (PR)

A small rodlet, usually a few centimetres in length and a few millimetres in diameter, containing an active substance, generally designed for direct application.

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	
2.1	Appearance: Physical state Colour		Data required before and after storage	Observations after storage should include rodlet integrity.
2.2	Explosive properties	A 14 UN RTDG Manual of Tests and Criteria	Not required after storage	
2.2	Oxidising properties	A 17 Test O.1 or O.3	Not required after storage	
2.3	Flammability and self-heating	A10, A16 Test N.1 Test N.4	Not required after storage	
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	
2.6	Bulk density	MT 186	Not required after storage	
2.8.5.3	Attrition	MT 178 or MT 193	Data required before and after storage	The data should demonstrate the robustness of the stick and it's stability in transport and use.
2.8.5.4	Hardness† and integrity	Visual observation (integrity)	Data required before and after storage	
2.7	Stability of packaging and packaging/preparation interactions		Data required before and after storage	Observation of pack stability including weight change.

† As of April 2018, there is no specific method for hardness, a CIPAC method is under consideration.

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4.7 Aerosols (AE)

A container-held formulation which is dispersed generally by a propellant as fine droplets or particles upon the actuation of a valve. Guidance on the testing of aerosols may be found in 'The Aerosol Directive' (75/324/EEC) and the subsequent amendment 94/1/EC. Additional methods for the determination of these aerosol specific properties (internal pressure / discharge rate) are included in the FAO / WHO manual.[18]

Annex point	Property	Test Method	Storage stability requirements	Comments
1.4.1	Active substance content	Appropriate validated method	Data required before and after storage	The net active substance content of the spray produced from the aerosol should be determined shall not be lower than that declared.
2.3	Flammability and self-heating		Not required after storage	Flammability should be tested in accordance with the methods described in Annex I, Part 2.3 of Regulation (EC) No. 1272/2008 and classified accordingly.
2.4	pH Acidity/ alkalinity (if applicable)	MT 75.3 MT 191 MT 31	Data required before and after storage	Applicable to water-based formulations only.
2.7	Stability of packaging and packaging/preparation interactions		Required before and after storage	Observations of pack stability including weight change. Indicate if there has been seepage/migration of the active substance. Observation of can integrity.
2.11	Weight loss of can after a 5 second spray (repeated three times)	No standard method	Required before and after storage	These data allow a measurement of the approximate application rate.
2.11	Spray pattern (note 1)	No standard method	Required before and after storage	Evidence is required that the container and nozzle/spray release mechanism remains intact on storage with no corrosion and that there is no nozzle blockage on storage (required after storage only).
2.11	Clogging of aerosol dispenser valves	See note 2	Required before and after storage	No clogging shall occur when tested in line with the method described below, see note 2.
2.11	Internal pressure	See FAO/WHO manual[14], AE	Required before and after storage	The determination of the pressure existing in the finished aerosol packs is necessary to verify that the

[18] Manual on development and use of FAO and WHO specifications for pesticides, 2016, 3rd revision of the 1st edition and any additional supplements.

		specification, note 8		true pressure is compatible with the pressure limitations of the pack, and in accordance with the regulations.
2.11	Discharge rate	See FAO/WHO manual[14], AE specification, note 9	Required before and after storage	

Note 1: Determined by measuring the diameter of the wet patch on a piece of cardboard (or similar material) when sprayed at a distance of 30 cm.

Note 2: Shake the aerosol dispensers thoroughly and, keeping them in an upright position, disperse the contents of each into the fume hood. Actuate the valve in a series of cycles (30 sec on, 30 sec off) until the dispenser is emptied. Examine the valves for clogging.

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Appendix 2: Compatibility Assurance Statement

…….. (product name)
Compatibility Assurance Statement

1. We …… (company name) report, as required by paragraph 2.9 of Part A of Regulation EU 284/2013, the physical and chemical compatibility of ……..(product name) with other products and substances, as listed on **[the following page/the attached draft label/the draft label submitted on (date)]***.

2. We confirm that the conditions of authorisation of those other products and substances under Regulation (EC) No. 1107/2009 concerning the placing of plant protection products on the market permit their use on the crops and [at the timing necessary] for their use in tank mix with …….. (Product name).

3. Evidence, which can be submitted on request, is available which indicates the physical and chemical compatibility of the current formulation of ……. (product name) with the products and substances listed and we have given careful consideration to the potential risk of any increase in hazard to the health of human beings, creatures and plants or to the environment, and to the risk of chemical incompatibility.

4. We certify that we know of no reason to believe that any of the above hazards are likely to be increased by use of the proposed mixtures and that, except where the draft text draws attention to any limitations, the evidence indicates that these mixtures should be fully satisfactory when used in accordance with the draft instructions for use of each product.

5. We confirm that any additional compatible mixtures that we recommend on the product label, verbally or via websites, advertising or other material will comply with the requirements of paragraphs 2 to 4 above and that these mixtures will be notified to HSE with a new Compatibility Assurance Statement at the next application for this product.

…….. (signature)
…… (position)
……. (date)

*** delete as appropriate (other wording may be used if appropriate to the specific case).**

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