agriculture,
forestry & fisheries

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REPUBLIC OF SOUTH AFRICA

GUIDELINES FOR REGISTRATION OF ADJUVANTS

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1. INTRODUCTION

The purpose of these guidelines is to assist applicants and other parties to meet registration requirements for adjuvants that are used in combination with agricultural remedies (e.g. pesticides/Plant Growth Regulators/biological remedies/legume inoculants/plant nutrients or foliar fertilizers) in South Africa. This guideline document should be read in conjunction with other guidelines published by the office of the Registrar of Act 36 of 1947. It should be noted that any combination of agricultural remedies/adjuvants plus fertilizers can only be approved if the requirements for the registration of agricultural remedies are met in full.

"**adjuvant**" means any chemical substance or biological remedy, or any mixture or combination of such substance or remedy and which, when it is added to an agricultural remedy which is prepared for application in accordance with the approved instructions for use of that agricultural remedy, will enhance the efficiency of such agricultural remedy. For the purposes of registration, an adjuvant should be classified based on the effect on the agricultural remedy to which it is added, which may be by enhancing the efficiency (Class A) and/or by modifying the carrier (Class B) of such an agricultural remedy (www.daff.gov.za).

An adjuvant may be incorporated in a formulation during the formulation process of an agricultural remedy and contained in the registered product. Alternatively, adjuvants are added to the spray tank and mixed with a registered product before application. Refer to section 5 below for various types of adjuvants. Adjuvants should not contain inert ingredients of concern that are already prohibited. Refer to the local Banned Substance List for further details on prohibited formulants.

Application for registration of an adjuvant is not required if an adjuvant is co-formulated in a registered product and the adjuvant is not added to the spray tank before application of the agricultural remedy. Where an adjuvant is a separate or stand-alone product recommended to be tank mixed with a registered agricultural remedy, this falls directly within a definition of an adjuvant as an agricultural remedy. In such situations, the adjuvant needs to be registered as stand-alone product in accordance with this guideline.

The data requirements for adjuvants are similar to those of agricultural remedies in general. It is the responsibility of an applicant to be familiar with such data requirements to be able to support any claims made on the proposed label. It should be noted that the herbicides registration guidelines may require testing of a double dosage rate whereas these guidelines refer to the highest rate of an agricultural remedy. Below is a summary of specific data requirements for adjuvants. Laboratory tests e.g. residue studies, 5 batch analyses, certificates of analysis should be carried out by an accredited (ISO 17025/OECD GLP) laboratory and toxicological studies should be carried out by OECD GLP accredited laboratory. Greenhouse trials can be replaced by field trials if such facilities are not available for trial purposes.

It is emphasised that certain adjuvant active ingredients or inert components within an adjuvant formulation, regardless of the adjuvant class, may have an implication on relevant maximum residue levels (MRL) for various crops. It is the responsibility of the applicant to be familiarised with such components and to provide residue analysis in such cases to ensure that the use of the adjuvant does not lead to MRL exceedance when used as recommended. Refer to Section 5.1.4 and 5.2.10 below for further details.

NOTE: If any of the data or documents called for in the paragraphs that follow are deemed by the applicant to be unnecessary or irrelevant, good scientific argument supporting this view should be presented in an application for a waiver of the requirement for such data or documentation. The application for waiver should be submitted before any tests/trials/studies are conducted and prior to the registration application being submitted to the office of the Registrar.

This document is effective from the 1st of January 2018 and it repeals the previous adjuvants guidelines. Registration holders will be allowed a period of five (5) years to adjust the existing labels to the new requirements as per these guidelines effective from the above-mentioned implementation date.

2. CHEMISTRY AND MANUFACTURE

The following information is required for registration application: Detail of the active constituent or minimum purity %, manufacturing process, either a 5 batch analysis or certificates of analysis (COAs), declaration of the full formulation composition, physical and chemical characteristics, product stability, details of analytical methods. A technical specification of the Effective Adjuvant Component (EAC) detailing the minimum content and the maximum levels (% w/w, g/l or g/kg) should be made available. All impurities generated from the manufacture of the active constituent which are of toxicological, eco-toxicological or environmental significance must be stated. The technical specification must use names in accordance with IUPAC, ELINCS/EINECS and/or CAS nomenclature.

3. FORMULATION COMPOSITION

The full formulation composition of the adjuvant must be provided. The details needed include chemical composition, concentration (% w/w, g/l or g/kg), colour index number for dyes as well as the purpose of all constituents in the formulated product. If the formulation does not contain a single active constituent, complete formulation details must be provided. A method of analysis for determining the Effective Adjuvant Component (EAC) should be provided. The basic physical and chemical properties should be in accordance with FAO formulation specifications relevant to a specific formulation.

4. FORMULATION TOXICITY DATA REQUIREMENTS

4.1 New active ingredient

This section applies to the requirements for registration of an agricultural remedy containing an active ingredient/product that has not yet been approved for use in South Africa.

Reports and summary on the pharmacology, toxicology and environmental impact studies of the active ingredient and its metabolites and/or degradation products according to OECD guidelines (6). These reports can be submitted on a compact disc (CD/DVD). If a remedy containing a new active ingredient is already registered by one or more of the registration authorities of the USA, EU, UK, Japan, Canada or Australia, toxicological risk assessment reports from the registration authorities concerned, together with a toxicological risk assessment, by an independent and accredited toxicologist, can be submitted in support of a provisional registration.

Information to determine the environmental fate of the major components of the adjuvant formulation is required, for example the rate of uptake, metabolism within the plants, hydrolytic stability, rate of photo-degradation, microbial degradation, persistence, half-life in soil and water, mobility in soil, effect on non-target organisms, wildlife, bees, fish, and other organisms, potential for accumulation and bio-accumulation should be submitted.

Reports and summary on formulation toxicity should be done according to OECD guidelines and test methods (6). These reports can be submitted on a compact disc (CD/DVD). The toxicological studies should be done in a laboratory which is OECD GLP accredited.

4.2 Generic active ingredient

This section applies to the registration of an agricultural remedy containing a generic active ingredient from a source other than that of a registered product.

The active ingredient of an adjuvant is classified as generic if the active content is within the following tolerances of the active content of the registered reference product:

Declared content in g/kg or g/ℓ at 20˚C	**Tolerance**
Up to 25	± 15% of the declared content for "homogenous" formulations (EC, SC, SL, etc.) **or** ± 25% for "heterogenous" 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
Note. In each range the upper limit is included.	

For all new formulations, it is required that formulation toxicity data, generated according to OECD Guidelines and using OECD GLP accredited laboratories (6), be submitted for hazard classification as per the latest regulations/guidelines).

4.3 Food-derived active ingredient

This section applies to the registration of an adjuvant containing an active ingredient which is derived from a food source.

Certain food sources may have the properties of an adjuvant and can, therefore, be formulated into an agricultural remedy. Active ingredients from these food sources are typically consumed by humans or animals and thus may be well known to have low toxicity and/or low impact on the environment. In such cases, products containing food derivatives may be exempt from supplying detailed toxicological data or hazard classification. An explanatory note should be given to the relevant Technical Advisor, with the request of the data waiver attached. This waiver should be granted before the application to register the adjuvant containing the food derivative is submitted for evaluation.

Active ingredients from food sources may have known allergenic potential to humans and thus pose a possible risk to those handling adjuvants containing such ingredients, as well as the end user of a treated commodity. Refer to the list of known allergenic substances (Annex 1) as well as the list of active ingredients prohibited for use in agricultural remedies and foliar feeds. For adjuvants containing active ingredients from food sources with a known allergenic potential, as listed in Annex 1, residue studies of the edible commodity from the treated plant should be submitted to confirm that the active is present at levels below those considered to be of allergenic potential to humans.

Food derivatives are common sources of dye, colourant, pigment and polymer active ingredients. However, these products may have an effect on the environment. Toxicology data is not required for adjuvants with active ingredients from these sources if these are already permissible under the Foodstuffs, Cosmetics and Disinfectants Act (Act 54 of 1972).

5. SPECIFIC DATA REQUIREMENTS FOR ADJUVANT TYPES

Adjuvants should be classified in the following groups:

Class A: Enhance efficiency of an agricultural remedy, includes

- Surfactants (Surface active agents)
- Oil adjuvants
- Stickers

Class B: Modify the carrier of an agricultural remedy, includes

- Buffers and acidifiers
- Salt adjuvants
- Deposition/Drift control agents
- Compatibility agents
- Anti-foam agents and defoaming agents
- Dyes, colourants or pigments for seeds
- Dyes, colourants, pigments or foam markers on plant material
- Seed adhesive polymers
- Brighteners

5.1. Class A Adjuvants

This class of adjuvants is applied with an agricultural remedy to improve the spreading, retention, absorption, penetration or sticking of the remedy to the target.

The number of trials required for registration of an adjuvant in these situations is dependent on whether the active ingredient of the adjuvant is novel or generic and to which group of pesticides or chemicals the agricultural remedy, with which the adjuvant will be tank mixed, belongs.

Groups of pesticides or chemicals will behave in a similar way when applied with a certain adjuvant and as such, the effect can be extrapolated within the group. For the purposes of registration of an adjuvant, seven types of agricultural remedies are defined with which an adjuvant may be registered: insecticides, fungicides, herbicides, biological remedies, foliar feeds, inoculants and plant growth regulators (PGRs). Information regarding some of the

active ingredients which fall into different groups within a type of agricultural remedy may be found online: insecticides (http://www.irac-online.org), fungicides (www.frac.info), herbicides (http://hracglobal.com/) and PGRs. Foliar feeds are divided into three groups based on the content of nitrogen, phosphorous and potassium or other nutrients. Currently, no extrapolation within foliar feeds, PGRs, biological products and inoculants is possible. Biological products referred to in this section, are those containing active ingredients which are non-living, excluding viruses. For data required for registration of adjuvants with living microbes, refer to section 5.4 below.

Efficacy and phytotoxicity requirements:

Refer to sections 5.1.1 – 5.1.3. for detailed data requirements for each type of Class A adjuvant.

For adjuvants containing novel active ingredients, full data sets must be submitted for 30% of the total number of groups for each agricultural remedy type claimed to be used with the adjuvant. For adjuvants containing generic active ingredients, full data sets must be submitted for the relevant Class A adjuvant for 10% of the total number of groups for each agricultural remedy type claimed to be used with the adjuvant. Adjuvant formulations containing a new mix of generic active ingredients will be treated as 'novel' for the purposes of data requirements, therefore full data sets must be submitted for 30% of the total number of groups for each agricultural remedy type claimed.

For example, if Adjuvant X contains a novel active ingredient and is to be claimed with 10 insecticide groups (e.g. IRAC groups 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10), data must be submitted for 3 of the claimed insecticide groups. If Adjuvant X contained a generic active ingredient and is to be claimed with 10 insecticide groups (e.g. IRAC groups 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10), data must be submitted for 1 of the claimed insecticide groups. A minimum of 1 full data set must be submitted for adjuvants with generic active ingredients regardless of the total number of groups claimed for that agricultural remedy type.

Please note that no extrapolation is possible between or within groups of biological products, PGRs, foliar feeds and inoculants. Refer to Section 5.4. for further requirements for biological products.

Residue data requirements for Class A adjuvants: Refer to Section 5.1.4. below.

5.1.1. Surfactants

Includes: wetting agents, wetters, spreading agents, spreaders, penetrants, surfactant-based penetrants, surface active agent, cationics/cationic surfactants, anionics/anionic surfactant, non-ionics/non-ionic surfactants, amphoterics/amphoteric surfactants, translocators, dispersing agents, organo-silicate surfactants, acidified surfactants and any combination thereof.

Function

These adjuvants are water soluble products that reduce the surface tension of spray droplets thereby improving spreading and may also increase retention. They can also enhance uptake of a systemic agricultural remedy by making the plant cuticle more receptive to absorption of an agricultural remedy. Surfactants can be amphoteric, non-ionic,

anionic or cationic in nature. Many agricultural remedies benefit from the use of surfactant adjuvants enabling comparable efficacy to be obtained with lower dosage rates, through the utilization of the above processes.

Registration requirements:

a) Laboratory testing:

Laboratory surface tension tests (tensiometer) or physical spreading measurements are required. This should be done by a validated or internationally recognised method. The validated method should be submitted or, in the case of a recognised method, the method should be clearly referenced.

Type	**No. Trials/Studies**	**Treatments**
Laboratory surface tension test (tensiometer) / physical spreading measurements	1	1) Untreated control: Distilled water 2) Highest recommended surfactant rate 3) Standard: Recommended rate of a registered surfactant

b) Field/Biological Efficacy and Phytotoxicity:

A minimum of three successful field trials must be done on the same crop type to demonstrate the efficacy of the surfactant with a single group of an insecticide, fungicide, herbicide, biological product, foliar feed, inoculant or PGR. Trials may be conducted over a single season provided that trials are located in three different bioclimatic areas. If this is not possible, trials should be conducted over a minimum of two seasons.

The number of groups for which a set of data must be submitted is dependent on whether the adjuvant contains novel active ingredients, generic active ingredients, or a new combination of generic active ingredients, and further, on how many groups of insecticides, fungicides, herbicides, biological products, foliar feeds, inoculants or PGRs are claimed. Refer to section 5.1. for further details.

Treatments to be included in trials:

- Untreated control
- Agricultural remedy at 50% of the lowest recommended rate + surfactant at the recommended rate
- Agricultural remedy at the lowest recommended rate + surfactant at the recommended rate*
- Agricultural remedy at the highest recommended rate + surfactant at the recommended rate
- Agricultural remedy at the highest recommended rate
- Agricultural remedy at the highest recommended rate + registered adjuvant standard at the recommended rate

* Treatment only relevant where a range of doses are recommended for an agricultural remedy for that crop.

Type	**No. Trials/ Studies**				**Treatments**
Novel active ingredient OR New combination of generic active ingredients		Bioclimatic Zones[a]			1) Untreated control 2) 50% of lowest recommended rate of agricultural remedy + surfactant at recommended rate 3) Lowest recommended rate of agricultural remedy + surfactant at recommended rate* 4) Highest recommended rate of agricultural remedy + surfactant at recommended rate 5) Highest recommended rate of the agricultural remedy 6) Highest recommended rate of the agricultural remedy + recommended rate of a registered adjuvant
		Climatic Zone 1	Climatic Zone 2	Climatic Zone 3	
Insecticides: For each group of the 30% of total number of IRAC groups claimed[b]	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Fungicides For each group of the 30% of total number of FRAC groups claimed[b]	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Herbicide For each group of the 30% of total number of HRAC groups claimed[b]	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
PGRs For each group of PGRs claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Biological Products For each group claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Inoculants For each group claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Foliar Feeds For each group	Total trials to submit: 3				
	Representative Agricultural	1	1	1	

claimed	Remedy on Representative Crop				

[a] Trials can be done over 1 growing season if these are in 3 different bioclimatic zones. If this is not possible, trials should be done over 2 growing seasons.
[b] To fulfil requirements for one group, a minimum of 3 trials on one crop type with a representative pesticide from that group should be submitted.

Generic active ingredient[c]		Bioclimatic Zones [d]			
		Climatic Zone 1	Climatic Zone 2	Climatic Zone 3	1) Untreated control 2) 50% of lowest recommended rate of agricultural remedy + surfactant at recommended rate 3) Lowest recommended rate of agricultural remedy + surfactant at recommended rate* 4) Highest recommended rate of agricultural remedy + surfactant at recommended rate 5) Highest recommended rate of the agricultural remedy 6) Highest recommended rate of the agricultural remedy + recommended rate of a registered adjuvant
Insecticides: For each group of the 10% of total number of IRAC groups claimed[e]	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Fungicides For each group of the 10% of total number of FRAC groups claimed[e]	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Herbicide For each group of the 10% of total number of HRAC groups claimed[e]	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
PGRs For each group of PGRs claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Biological Products For each group claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Inoculants For each group claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Foliar Feeds	Total trials to submit: 3				

For each group claimed	Representative Agricultural Remedy on Representative Crop	1	1	1	

[c] This includes adjuvants which contain active ingredients already registered in South Africa applying for a generic claim on an approved end use with an approved GAP; generic adjuvants claiming a new end use; generic adjuvants claiming use with a new group of agricultural remedies; and generic adjuvants claiming a change in GAP. Common changes in GAP include: application rate, application interval, number of applications and growth stage of application.
[d] Trials can be done over 1 growing season if these are in 3 different bioclimatic zones. If this is not possible, trials should be done over 2 growing seasons.
[e] To fulfil requirements for one group, a minimum of 3 trials on one crop type with a representative pesticide from that group should be submitted.

5.1.2. Oil Adjuvants

Includes: crop oil concentrates (COC), crop oils (CO), plant oils, seed oils, methylated seed oils (MSO), vegetable oils, vegetable oil concentrates (VOC), esterified vegetable oils, petroleum oils (light, medium or heavy), mineral oils, paraffinic oils, high surfactant oil concentrate (HSOC), oil penetrants, penetrants and any combination thereof.

Function

These adjuvants are usually water insoluble products that decrease the surface tension of spray droplets to increase retention and spreading. They can also aid in the absorption of systemic agricultural remedies by making the plant cuticle more receptive to agricultural remedy absorption. Oils are typically from plant or petroleum origin. Various agricultural remedies require the use of oils to optimize delivery to the target in addition to aiding the absorption process of systemic agricultural remedies.

Registration requirements:

a) Laboratory testing:

Laboratory surface tension tests (tensiometer) or physical spreading measurements are required. This should be done by a validated or internationally recognised method. The validated method should be submitted or, in the case of a recognised method, the method should be clearly referenced.

Type	**No. Trials/Studies**	**Treatments**
Laboratory surface tension test (tensiometer) / physical spreading measurements	1	1) Untreated control: Distilled water 2) Highest recommended oil adjuvant rate 3) Standard: Recommended rate of a registered oil adjuvant

b) Field/Biological Efficacy and Phytotoxicity:

A minimum of three successful field trials must be done on the same crop type to demonstrate the efficacy of the oil adjuvant with a single group of an insecticide, fungicide, herbicide, biological product, foliar feed, inoculant or PGR. Trials may be conducted over a single season provided that trials are located in three different bioclimatic areas. If this is not possible, trials should be conducted over a minimum of two seasons.

The number of groups for which a set of data must be submitted is dependent on whether the adjuvant contains novel active ingredients, generic active ingredients, or a new combination of generic active ingredients, and further, on how many groups of insecticides, fungicides, herbicides, biological products, foliar feeds, inoculants or PGRs are claimed. Refer to section 5.1. for further details.

Treatments to be included in trials:

- Untreated control
- Agricultural remedy at 50% of the lowest recommended rate + oil adjuvant at the recommended rate
- Agricultural remedy at the lowest recommended rate + oil adjuvant at the recommended rate*
- Agricultural remedy at the highest recommended rate + oil adjuvant at the recommended rate
- Agricultural remedy at the highest recommended rate
- Agricultural remedy at the highest recommended rate + registered adjuvant standard at the recommended rate

* Treatment only relevant where a range of doses are recommended for an agricultural remedy for that crop.

<table>
<tr><th>Type</th><th colspan="4">No. Trials/ Studies</th><th>Treatments</th></tr>
<tr><td rowspan="2">Novel active ingredient
OR
New combination of generic active ingredients</td><td rowspan="2"></td><td colspan="3">Bioclimatic Zones[a]</td><td rowspan="7">1) Untreated control
2) 50% of lowest recommended rate of agricultural remedy + oil adjuvant at recommended rate
3) Lowest recommended rate of agricultural remedy + oil adjuvant at recommended rate*
4) Highest recommended rate of agricultural remedy + oil adjuvant at recommended rate
5) Highest recommended rate of the agricultural remedy
6) Highest recommended</td></tr>
<tr><td>Climatic Zone 1</td><td>Climatic Zone 2</td><td>Climatic Zone 3</td></tr>
<tr><td rowspan="2">Insecticides:

For each group of the 30% of total number of IRAC groups claimed[b]</td><td colspan="4">Total trials to submit: 3</td></tr>
<tr><td>Representative Agricultural Remedy on Representative Crop</td><td>1</td><td>1</td><td>1</td></tr>
<tr><td rowspan="2">Fungicides

For each group of the 30% of total number of FRAC groups claimed[b]</td><td colspan="4">Total trials to submit: 3</td></tr>
<tr><td>Representative Agricultural Remedy on Representative Crop</td><td>1</td><td>1</td><td>1</td></tr>
</table>

Herbicide For each group of the 30% of total number of HRAC groups claimed[b]	Total trials to submit: 3				rate of the agricultural remedy + recommended rate of a registered adjuvant
	Representative Agricultural Remedy on Representative Crop	1	1	1	
PGRs For each group of PGRs claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Biological Product For each group claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Inoculants For each group claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Foliar Feeds For each group claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	

[a] Trials can be done over 1 growing season if these are in 3 different bioclimatic zones. If this is not possible, trials should be done over 2 growing seasons.
[b] To fulfil requirements for one group, a minimum of 3 trials on one crop type with a representative pesticide from that group should be submitted.

Generic active ingredient[c]		Bioclimatic Zones [d]			
		Climatic Zone 1	Climatic Zone 2	Climatic Zone 3	1) Untreated control 2) 50% of lowest recommended rate of agricultural remedy + oil adjuvant at recommended rate 3) Lowest recommended rate of agricultural remedy + oil adjuvant at recommended rate* 4) Highest recommended rate of agricultural remedy + oil adjuvant at recommended rate 5) Highest recommended
Insecticides: For each group of the 10% of total number of IRAC groups claimed[e]	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Fungicides For each group of the 10% of total number of FRAC groups claimed[e]	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	

Herbicide For each group of the 10% of total number of HRAC groups claimed[e]	Total trials to submit: 3				rate of the agricultural remedy 6) Highest recommended rate of the agricultural remedy + recommended rate of a registered adjuvant
	Representative Agricultural Remedy on Representative Crop	1	1	1	
PGRs For each group of PGRs claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Biological Product For each group claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Inoculants For each group claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Foliar Feeds For each group claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	

[c] This includes adjuvants which contain active ingredients already registered in South Africa applying for a generic claim on an approved end use with an approved GAP; generic adjuvants claiming a new end use; generic adjuvants claiming use with a new group of agricultural remedies; and generic adjuvants claiming a change in GAP. Common changes in GAP include: application rate, application interval, number of applications and growth stage of application.
[d] Trials can be done over 1 growing season if these are in 3 different bioclimatic zones. If this is not possible, trials should be done over 2 growing seasons.
[e] To fulfil requirements for one group, a minimum of 3 trials on one crop type with a representative pesticide from that group should be submitted.

5.1.3 Stickers

Includes: sticker agents, adhesive agents, extenders, pinenes, terpenic polymers, di-1-p-methenes, poly-1-p-menthenes, latex, pyrrolidone-based agents, waxes and any combination thereof.

Function

Stickers are designed to increase target contact, resist wash-off, erosion etc. of spray droplet residuals for an extended period after agricultural remedy application. They may, however, also aid in the absorption of systemic agricultural remedies in an indirect way because of an extended absorption time.

Registration requirements:

a) Laboratory testing:

Some proof of residual extension period should be provided i.e. scanning electron micrographs, visual observation of residuals, time lapse photography or any other validated or internationally recognised method. The validated method should be submitted or, in the case of a recognised method, the method should be clearly referenced.

Type	**No. Trials/Studies**	**Treatments**
Laboratory / Glasshouse study	1	1) Untreated control: Distilled water 2) Highest recommended sticker adjuvant rate 3) Standard: Recommended rate of a registered sticker adjuvant Appropriate measurements to be taken, for example: Simulated Rainfastness – [i.e. Cu detection test; UV dye]

b) Field/Biological Efficacy and Phytotoxicity:

A minimum of three successful field trials must be done on the same crop type to demonstrate the efficacy of the sticker with one group of an insecticide, fungicide, herbicide, biological product, foliar feed, inoculant or PGR. Trials may be conducted over a single season provided that trials are located in three different bioclimatic areas. If this is not possible, trials should be conducted over a minimum of two seasons.

The number of groups for which a set of data must be submitted is dependent on whether the adjuvant contains novel active ingredients, generic active ingredients, or a new combination of generic active ingredients, further, as to how many groups of insecticides, fungicides, herbicides, biological products, foliar feeds, inoculants or PGRs are claimed. Refer to section 5.1 for further details.

Treatments to be included in trials:

- Untreated control
- Agricultural remedy at 50% of the lowest recommended rate + sticker at the recommended rate
- Agricultural remedy at the lowest recommended rate + sticker at the recommended rate*
- Agricultural remedy at the highest recommended rate + sticker at the recommended rate
- Agricultural remedy at the highest recommended rate
- Agricultural remedy at the highest recommended rate + registered adjuvant standard at the recommended rate

* Treatment only relevant where a range of doses are recommended for an agricultural remedy for that crop.

Type	**No. Trials/ Studies**				**Treatments**
Novel active ingredient OR New combination of generic active ingredients		Bioclimatic Zones[a]			1) Untreated control 2) 50% of lowest recommended rate of agricultural remedy + sticker at recommended rate 3) Lowest recommended rate of agricultural remedy + sticker at recommended rate* 4) Highest recommended rate of agricultural remedy + sticker at recommended rate 5) Highest recommended rate of the agricultural remedy 6) Highest recommended rate of the agricultural remedy + recommended rate of a registered adjuvant
		Climatic Zone 1	Climatic Zone 2	Climatic Zone 3	
Insecticides: For each group of the 30% of total number of IRAC groups claimed[b]	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Fungicides For each group of the 30% of total number of FRAC groups claimed[b]	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Herbicide For each group of the 30% of total number of HRAC groups claimed[b]	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
PGRs For each group of PGRs claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	

Biological Product For each group claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Inoculants For each group of claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Foliar Feeds For each group of claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	

[a] Trials can be done over 1 growing season if these are in 3 different bioclimatic zones. If this is not possible, trials should be done over 2 growing seasons.
[b] To fulfil requirements for one group, a minimum of 3 trials on one crop type with a representative pesticide from that group should be submitted.

Generic active ingredient[c]		Bioclimatic Zones [d]			
		Climatic Zone 1	Climatic Zone 2	Climatic Zone 3	1) Untreated control 2) 50% of lowest recommended rate of agricultural remedy + sticker at recommended rate 3) Lowest recommended rate of agricultural remedy + sticker at recommended rate* 4) Highest recommended rate of agricultural remedy + sticker at recommended rate 5) Highest recommended rate of the agricultural remedy 6) Highest recommended rate of the agricultural remedy + recommended rate of a registered adjuvant
Insecticides: For each group of the 10% of total number of IRAC groups claimed[e]	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Fungicides For each group of the 10% of total number of FRAC groups claimed[e]	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Herbicide For each group of the 10% of total number of HRAC groups claimed[e]	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
PGRs For each group of PGRs claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	

Biological Product For each group claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Inoculants For each group claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	
Foliar Feeds For each group claimed	Total trials to submit: 3				
	Representative Agricultural Remedy on Representative Crop	1	1	1	

[c] This includes adjuvants which contain active ingredients already registered in South Africa applying for a generic claim on an approved end use with an approved GAP; generic adjuvants claiming a new end use, generic adjuvants claiming use with a new group of agricultural remedies and generic adjuvants claiming a change in GAP. Common changes in GAP include: application rate, application interval, number of applications and growth stage of application.

[d] Trials can be done over 1 growing season if these are in 3 different bioclimatic zones. If this is not possible, trials should be done over 2 growing seasons.

[e] To fulfil requirements for one group, a minimum of 3 trials on one crop type with a representative pesticide from that group should be submitted.

5.1.4. Residue requirements for Class A adjuvants

Class A adjuvants, or adjuvants containing one or more active ingredients functioning as a Class A adjuvant, may affect residue breakdown of the agricultural remedy with which it is applied, in or on the plant. Therefore, when testing agricultural remedies with a label allowance for the use of a Class A adjuvant, field residue trials must be conducted and should include the recommended adjuvant applied according to the highest recommended rate. This information must be recorded in the laboratory residue test report. In such cases it will not be necessary to determine residues both with and without the addition of the adjuvant.

If an adjuvant is to be registered for use with already registered agricultural remedy(ies), trials will be needed to demonstrate compliance with Maximum Residue Limits of the agricultural remedy(ies) concerned. These trials should be done with the maximum recommended rates of both the adjuvant and the agricultural remedy(ies). In such cases it will not be necessary to determine residues both with and without the addition of the adjuvant.

In cases where the active ingredient of the adjuvant itself, or components of the adjuvant, are known to have an MRL implication and a set ADI (average daily intake) e.g. phosphonates; residue analysis must be provided for all claims submitted which are relevant for export crops, as well as those claims for which a withholding period of 7 days

and less. For these adjuvants, a recommended withholding period on relevant crops must be proposed.

For adjuvants containing novel active ingredients being registered for use with already registered agricultural remedies, the following residue data sets will be needed:

Three residue data sets, each of which with a different chemical group (Insecticide, Fungicide, Herbicide, PGR, foliar feed, biological product or Inoculant) as claimed. Each data set should contain trials done on one representative crop for which its use is proposed. Treatments should include the agricultural remedy applied at the highest recommended rate with the adjuvant applied at the highest recommended rate. Care should be taken to select representative crops with the lowest PHI. Residue data will only be required if the PHI is 7 days or less on the agricultural remedy labels used.

For adjuvants containing generic active ingredients being registered for use with already registered agricultural remedies, the following residue data sets will be needed:

At least 1 residue data set covering the worst case scenario i.e. the most sensitive or valuable crop and the lowest PHI. The data set should contain trials done on one representative crop for which its use is proposed. Treatments should include the agricultural remedy applied at the highest recommended rate with the adjuvant applied at the highest recommended rate. Care should be taken to select representative crops with the lowest PHI. Residue data will only be required if the PHI is 7 days or less on the agricultural remedy labels used.

For both new and generic adjuvants, residue data will be required if the PHI is 7 days or less on the pesticide labels used.

NOTE In the situations referred to above, a residue data set is defined in accordance with the latest residue guidelines as published (13) i.e. 5 trials in the case of major crops and 3 trials in the case of minor crops.

Macro and micro-organisms are mainly exempted from residue analysis. Consider published MRL information for further guidance. However, where such organisms are mixed with other agricultural remedies or adjuvants with MRL implications, residue data for the whole tank mix will be required if the PHI of any of the components in the tank mix is 7 days or less.

5.2. Class B Adjuvants

This class of adjuvants is applied to the tank alongside an agricultural remedy to improve the characteristics of the carrier of the agricultural remedy and does not have a direct impact on the agricultural remedy itself.

The number of trials required for registration of an adjuvant in these situations is dependent on the function of the adjuvant and is detailed below. For sections 5.2.2. – 5.2.6. below, efficacy trials should make use of a registered agricultural remedy or foliar feed. As the activity of the adjuvant is not directly related to the target of the active ingredient, it is not necessary to prove the efficacy of the adjuvant with every group of agricultural remedies/foliar feed claimed. Care should be taken to select a situation that could be considered the worst case scenario e.g. high value crop, most sensitive crop.

A laboratory-based compatibility test should also be submitted using a representative agricultural remedy for each formulation type that the adjuvant claims compatibility with.

Biological products referred to in this section, are those containing active ingredients which are non-living, excluding viruses. For data required for registration of adjuvants with living microbes, refer to section 5.4 below.

5.2.1. Buffers and acidifiers

Includes: acidifying agents, buffering agents, neutralisers, water conditioners, sequestering agents, organic acids, alkali's, inorganic acids and phosphonate acids and any combination thereof.

Function

The function of this adjuvant group is to modify the carrier of an agricultural remedy: to decrease, increase or maintain the pH of carrier water to the optimal pH for the activity of the agricultural remedy. These adjuvants are used with many agricultural remedies that are pH sensitive.

Registration requirements:

a) Laboratory testing:

Titration curves need to be carried out with various water carriers to establish if the desired pH range is reached using the target rate of buffer. It is recommended to test at least three types of water to establish buffering capacity:

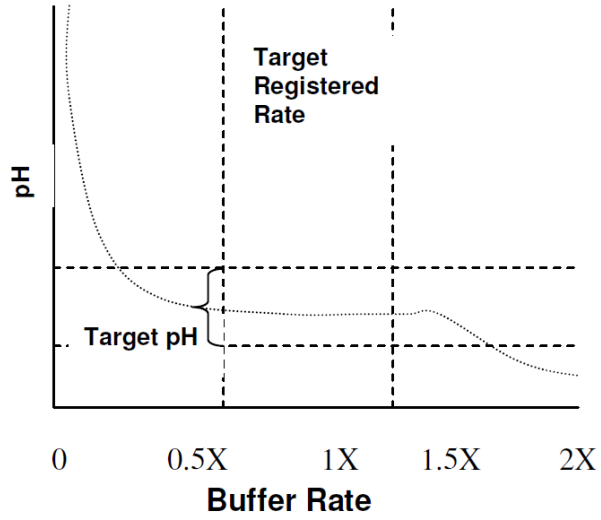
(i) Standard water (< 50 mg/L bicarbonate as sodium bicarbonate).
(ii) Buffered water (> 150 mg/L bicarbonate as sodium bicarbonate).
(iii) Highly buffered water (> 400 mg/L bicarbonate as sodium bicarbonate).

The titration curve should have at least five points, starting at a zero rate (pH of water before adding buffer) and ending in double the recommended rate of the buffer: i.e. no buffer; half the recommended rate; the recommended rate; one and a half times the recommended rate; double the recommended rate.

If the product fails to buffer one or more of these waters, the limitations should be clearly indicated on the label. It must be understood that no single product can buffer all water types to exactly the same level.

The waters used in the study can be of natural origin, but if such sources cannot be found which conform to (i), (ii) and (iii) above, they can be made up artificially with laboratory chemicals.

Example of a titration curve:



Type	No. Trials/Studies	Treatments
Laboratory titration curve: This must be done at an ISO 17025, GLP or accredited laboratory The validated method should be submitted or, in the case of a recognised method, the method should be clearly referenced.	1	1) Standard water a. Candidate adjuvant – rates to be included: 0; 0.5x; 1x; 1.5x; 2x. b. Registered adjuvant (similar chemistry) – rates to be included: 0; 0.5x; 1x; 1.5x; 2x. 2) Buffered water a. Candidate adjuvant – rates to be included: 0; 0.5x; 1x; 1.5x; 2x. b. Registered adjuvant (similar chemistry) – rates to be included: 0; 0.5x; 1x; 1.5x; 2x. 3) Highly buffered water a. Candidate adjuvant – rates to be included: 0; 0.5x; 1x; 1.5x; 2x. b. Registered adjuvant (similar chemistry) – rates to be included: 0; 0.5x; 1x; 1.5x; 2x.

b) Field/Biological Efficacy and Phytotoxicity:

Not applicable since the activity of this type of adjuvant is only to optimise the carrier and not the agricultural remedy.

NOTE: The product label for this type of adjuvant should include a warning to farmers to test their water quality regularly to ensure that the addition of a buffer or acidifier is definitely necessary.

5.2.2. Salt adjuvants

Includes: salts, ammonium-derivatives, water conditioners, sequestering agents, fertilizer adjuvants.

Function

The function of this adjuvant group is to reduce or eliminate salt antagonism from dissolved antagonistic salts in carrier water. In most cases, these adjuvants contain ammonium sulphate or other ammonium compounds.

Registration requirements:

a) Laboratory and glasshouse testing:

Toxicology or residues data will be required for those adjuvants that may have dietary risk requirements (eg phosphonic acid, etc). Refer to the residue guidelines. The water carriers in this study should include the following:

(i) Distilled or soft water (< 50 mg/L total dissolved salts).
(ii) Hard water (calcium - $CaCl_2$, or magnesium - $MgCl_2$ at >300 mg/L of the cation).
(iii) Brackish water (sodium - $NaHCO_3$ or NaCl at >300 mg/L of the cation).

These carriers can be either of natural or lab origin.

	No. Trials/Studies	**Treatments**
Greenhouse study	1	1) Distilled or soft water [< 50 mg/L Total dissolved salts] a. Sub-lethal[a] rate of agricultural remedy with half the recommended rate of the adjuvant b. Sub-lethal[a] rate of agricultural remedy with the recommended rate of the adjuvant c. Recommended rate of agricultural remedy with half the recommended rate of the adjuvant d. Recommended rate of agricultural remedy with the recommended rate of the adjuvant

		e. Registered standard at the recommended rate. 2) Hard water [+300 mg/ℓ Ca &/or Mg as $CaCl_2$ or $MgCl_2$] a. Sub-lethal[a] rate of agricultural remedy with half the recommended rate of the adjuvant b. Sub-lethal[a] rate of agricultural with the recommended rate of the adjuvant c. Recommended rate of agricultural remedy with half the recommended rate of the adjuvant d. Recommended rate of agricultural remedy with the recommended rate of the adjuvant e. Registered standard at the recommended rate. 3) Brackish water [+300 mg/ℓ Na as $NaHCO_3$] a. Sub-lethal[a] rate of agricultural remedy with half the recommended rate of the adjuvant b. Sub-lethal[a] rate of agricultural remedy with the recommended rate of the adjuvant c. Recommended rate of agricultural remedy with half the recommended rate of the adjuvant d. Recommended rate of agricultural remedy with the recommended rate of the adjuvant e. Registered standard at the recommended rate.
[a] Sub-lethal rate: a rate lower than the registered rate of the agricultural remedy which is not capable of achieving claimed efficacy (i.e. achieves approximately 60 – 70% control). This rate will critically challenge the ability of the adjuvant to stabilise the water quality.		

NOTE: The product label for this type of adjuvant should include a warning to farmers to test their water quality regularly to ensure that the addition of a salt adjuvant is definitely necessary.

5.2.3. Deposition agents and Anti-evaporants

Includes: deposition agents, drift reduction agents, drift retardants, anti-evaporants, anti-drift adjuvants and drift control adjuvants and any combination thereof.

5.2.3.1. Deposition/Drift control agents

Function

The purpose of deposition / drift control agents is to minimize the volume of small droplets in the spray cloud that have the potential to remain airborne for a period long enough to drift outside and away from the intended target area, and to settle onto non-target areas where it may cause adverse results. Generally, the aim would be to decrease the volume of droplets smaller than 200 micron diameter in the spray cloud.

Registration requirements:

a) Laboratory testing

Proof of the reduction of volume and number of driftable droplets and / or increase in the Volume Mean Diameter (VMD) of the droplet size spectrum must be provided. The validated method should be submitted or, in the case of a recognised method, the method should be clearly referenced. The following parameters are indicative of drift reduction:

- a reduction in the distance that droplets are drifting under comparable wind and humidity conditions,
- a reduction in the number of fine droplets per square centimeter over a distance.

Due to the fact that a field efficacy trial with different treatments, with and without a drift control product, is highly sensitive to wind and humidity conditions which change over time, it is very difficult to obtain reliable, comparable results on droplet spectra and coverage with field trials.

It is thus recommended that the following laboratory generated efficacy data be presented:

- Spraying water sensitive cards at the same nozzle and pressure setting with and without the drift retardant product. Droplet stains should be measured and changes in droplet spectra and reduction of % volume of fine droplets (smaller than 200 micron diameter) calculated.
- If available, proof of laser analysis of the droplet spectrum, showing an increase in the VMD and reduction in the % volume of fine droplets smaller than 200 micron can also be provided.

In addition, field trials should be submitted indicating the absence of antagonism of the adjuvant with the agricultural remedy i.e. the efficacy of the agricultural remedy is the same or improved by the addition of the adjuvant. If aerial application is claimed, one aerial trial should be submitted. If ground application is claimed, two field trials should be submitted.

Treatments to be used in the trials are:

- Highest recommended rate of adjuvant with the highest recommended rate of agricultural remedy
- Untreated control: water

b) Phytotoxicity

As deposition/drift control agents are predominantly intended for use with herbicides such as glyphosate and sulfonylurea, that are used on crops such as glyphosate tolerant crops (glyphosate) or wheat (sulfonylureas), it is necessary that the adjuvant be tested on 2 of the following 3 crops with a minimum of 3 trials submitted in total:

- Glyphosate tolerant maize
- Glyphosate tolerant soy beans
- Wheat

Treatments to be used in the trials are:

- Highest recommended rate of adjuvant with the highest recommended rate of agricultural remedy
- Untreated control: Distilled water

Treatments using double the recommended rates of polymer type drift control agents may produce application problems due to increased viscosity of the spray mixture and are therefore not necessary to include in trials.

5.2.3.2 Anti-evaporants

Function

The purpose of anti-evaporants is to retard the evaporation of droplets which are classified as fine or very fine droplets (< 200 micron), under low humidity conditions before reaching the target area, to ensure that a sufficient number of droplets will still reach the target area.

Registration requirements:

a) Laboratory testing:

Proof that a fine droplet spectrum will still provide effective coverage under low relative humidity conditions must be provided. The validated method should be submitted or, in the case of a recognised method, the method should be clearly referenced.

Due to the fact that an efficacy field trial with different treatments, with and without an anti-evaporant, is highly sensitive to wind and humidity conditions which change over time, it is very difficult to obtain reliable, comparable results on droplet spectra and coverage with field efficacy trials.

It is thus recommended that the following laboratory generated efficacy data be presented:

Data should confirm deposition of at least 50 droplets / cm^2 (the minimum required for effective contact fungicide application) following application from a 3 metre height under a 40% relative humidity, using a spinning disc atomiser spraying a fine droplet spectrum (VMD less than 200 micron) at a 20 litre per hectare rate.

In addition, field trials should be submitted indicating the absence of antagonism of the adjuvant with the agricultural remedy i.e. the efficacy of the agricultural remedy is the same or improved by the addition of the adjuvant. If aerial application is claimed, one aerial trial should be submitted. If ground application is claimed, two field trials should be submitted.

Treatments to be used in the trials are:

- Highest recommended rate of adjuvant with the highest recommended rate of agricultural remedy
- Untreated control: water

b) Phytotoxicity:

As anti-evaporants are intended for use with mainly insecticides and fungicides at reduced volume application rates, it is necessary that the anti-evaporant be tested on 2 of the following 6 crops with a minimum of 3 trials submitted in total:

- Maize or wheat
- Bean
- Potato
- Apples or pears
- Citrus
- Cabbage

Treatments to be used in the trials are:

- Highest recommended rate of adjuvant with highest the recommended rate of agricultural remedy
- Untreated control: water

5.2.4. Compatibility agents

Function

The purpose of compatibility agents is to improve the physical compatibility of components or agricultural remedies in the spray tank.

Registration requirements:

Type	**No. Trials/Studies**	**Treatments**
Laboratory test to confirm physical compatibility enhancement between 2 agricultural remedies known for their incompatibility: Observations on any separation, flocculation and precipitation should be included. The validated method should be submitted or, in the case of a recognised method, the method should be clearly referenced.	1	Tests should be conducted using distilled or soft water [< 50 mg/L Total dissolved salts] with each of the rates listed below (1 - 3) 1) Highest recommended rate of agricultural remedy A with the highest recommended rate of agricultural remedy B 2) Highest recommended rate of agricultural remedy A with the highest recommended rate of agricultural remedy B and the adjuvant at the highest recommended rate 3) Standard: Highest recommended rate of agricultural remedy A with the highest recommended rate of agricultural remedy B and the highest recommended rate of a registered compatibility adjuvant
Field trials to confirm the absence of antagonism and phytotoxicity as a result addition of the adjuvant to 2 agricultural remedies known for their incompatibility	2[a]	Tests should be conducted using distilled or soft water [< 50 mg/L Total dissolved salts] with each of the rates listed below (1 - 3) 1) Highest recommended rate of agricultural remedy A with the highest recommended rate of agricultural remedy B 2) Highest recommended rate of agricultural remedy A with the highest recommended rate of agricultural remedy B and the adjuvant at the highest recommended rate 3) Standard: Highest recommended rate of agricultural remedy A with the highest recommended rate of agricultural remedy B and the highest recommended rate of a registered compatibility adjuvant
[a] Field trials should be conducted over a single growing season on one crop type in different bioclimatic zones or, if this is not possible, over two growing seasons.		

5.2.5. Anti-foam and defoaming agents

Function

Anti-foam agents are low foaming products which prevent foam formation when agricultural remedies are mixed in the spray tank and Defoaming agents function after the formation of foam by physically breaking down the foam in the spray tank.

Registration requirements:

Type	**No. Trials/Studies**	**Treatments**
Laboratory test to confirm physical breakdown of foam. Measurement of foam volume should be included. The validated method should be submitted, in the case of a recognised method, the method should be clearly referenced.	1	1) Untreated control: water 2) Highest recommended rate of agricultural remedy 3) Highest recommended rate of agricultural remedy with adjuvant at the highest recommended rate 4) Highest recommended rate of agricultural remedy + registered adjuvant standard at the highest recommended rate (if available)
Field trials to confirm the absence of antagonism and phytotoxicity as a result addition of the adjuvant to an agricultural remedy known to produce foam	2[a]	1) Untreated control: water 2) Highest recommended rate of agricultural remedy 3) Highest recommended rate of agricultural remedy with adjuvant at the highest recommended rate 4) Highest recommended rate of agricultural remedy + registered adjuvant standard at the highest recommended rate (if available)
[a] Field trials should be conducted over a single growing season on one crop type in different bioclimatic zones or, if this is not possible, over two growing seasons.		

5.2.6. Dyes, colourants or pigments for seeds

Function

These are adjuvants which are applied with agricultural remedies to seed before planting. If treated with toxic chemicals the seed must, by law, be coloured so that this is recognisable, until the seed is planted.

Registration requirements

Trial requirements listed below must be considered along with current Guidelines for Seed Treatment Registration Trials. The validated method for laboratory tests used should be submitted or, in the case of a recognised method, the method should be clearly referenced.

Type	No. Trials/Studies	Treatments
Longevity of Adjuvant on the seed: [a] Laboratory test to prove that the seed colourant will remain on the seed for a period of 2 years. [b]	1	1) Highest recommended rate of adjuvant with the highest recommended rate of agricultural remedy
Phytotoxicity and germination trials: [a] Laboratory or Greenhouse trial Field trial	 1 2[c]	a. Untreated control b. Highest recommended rate of adjuvant with the highest recommended rate of agricultural remedy
[a] It is recommended that seed used in tests have a viability status which approximates the minimum generation requirement under the Plant Improvement Act (Act 53/1976). [b] This is the expected period that the seed can be carried over for, after treatment, i.e. the shelf life of the seed. [c] Field trials should be conducted over a single growing season on one crop type in different bioclimatic zones or, if this is not possible, over two growing seasons.		

5.2.7. Dyes, colourants, pigments or foam markers on plant material

Function

The purpose of these adjuvants is to mark spray swaths or places where agricultural remedies have been applied to avoid reapplication.

Registration requirements:

Type	No. Trials/Studies	Treatments
Longevity of product on plant material: Field trials Test to prove that the dye, colourant, pigment or foam marker will last on the plant material for the period claimed on the label and will not be phytotoxic or harm plant material	3[a]	1) Untreated control 2) Highest recommended rate of adjuvant
[a] Trials may be done in a single growing season on one crop covering dryland as well as irrigated crops		

in different bioclimatic zones or, if this is not possible, over two growing seasons. Indicate rainfall and irrigation volumes over the trial period where applicable.

5.2.8. Seed adhesive polymers

Function

Seed adhesive polymers improve the physical, physiological and sanitary characteristics of seed performance.

Registration requirements:

Trial requirements listed below must be considered along with current Guidelines for Seed Treatment Registration Trials. The validated method for laboratory tests used should be submitted or, in the case of a recognised method, the method should be clearly referenced.

Type	**No. Trials/Studies**	**Treatments**
Longevity and Adhesive Properties of Seed adhesive polymers on the seed: [a] Laboratory test to prove seed polymer has adhesive properties to reduce dust off etc. from the seed, and that the polymers will last on the seed for the period claimed on the label.	1	1) Untreated control 2) Highest recommended rate of adjuvant
Phytotoxicity and germination trials: [a] Laboratory or Greenhouse trial Field trial Test to prove that the seed adhesive polymers will not be phytotoxic to the seed or harm germination over one or more seasons [b]	 1 2[c]	: a. Untreated control b. Highest recommended rate of adjuvant and agricultural remedy

[a] It is recommended that seed used in tests have a viability status which approximates the minimum generation requirement under the Plant Improvement Act (Act 53/1976).
[b] This is the expected period that the seed can be carried over for after treatment, i.e. the shelf life of the seed.
[c] Field trials should be conducted over a single season on one crop type in different bioclimatic zones.

5.2.9. Brighteners

Function

Brighteners are ultraviolet (UV) protectants which may also influence the insecticidal properties of viruses.

Registration requirements:

Type	No. Trials/Studies	Rates/Target
Field trials	3[a]	1) Untreated control 2) Half of the recommended rate of agricultural remedy with brightener at the recommended rate 3) Highest recommended rate of agricultural remedy with brightener at the highest recommended rate 4) Highest recommended rate of agricultural remedy 5) Highest recommended rate of agricultural remedy with the highest recommended rate of registered adjuvant standard (if available)
[a] Field trials should be conducted on one crop type in different bioclimatic zones or, if this is not possible, over two growing seasons.		

These requirements are not applicable to testing adjuvants combined with biological products containing living organisms. For testing requirements based on such products, refer to section 5.4.3 below.

5.2.10. Residue requirements for Class B adjuvants

Class B adjuvants affect the carrier of the pesticide and not the pesticide itself and, therefore, do not affect the residue breakdown of the pesticide in or on the plant. Residue trials are therefore not required for the registration of an adjuvant containing **ONLY** Class B adjuvants.

However, in cases where the active ingredient of the adjuvant itself, or components of the adjuvant, are known to have an MRL implication e.g. phosphonates; residue analysis must be provided for all claims submitted which are relevant for export crops, as well as those claims for which a withholding period of 7 days and less is claimed for the relevant component, regardless of an adjuvant being classified as Class B. For these adjuvants, a recommended withholding period on relevant crops must be proposed.

Macro and micro-organisms are mainly exempted from residue analysis. Consider published MRL information for further guidance. However, where such organisms are mixed with other agricultural remedies or adjuvants with MRL implications, residue data for the whole tank mix will be required if the PHI of any of the components in the tank mix is 7 days or less.

5.3 Adjuvants with both Class A and Class B properties

If an adjuvant contains an active ingredient that has functions falling into Class A and Class B categories, or more than one active ingredient, such that the final formulation has functions falling into both Class A and Class B categories, data requirements for registration are as follows:

a) Laboratory tests as defined in 5.1 and 5.2 above for each of the functions claimed.
b) Field efficacy and phytotoxicity trials as defined in section 5.1 for each Class A claim.
c) Residue trials as defined in section 5.1.4.

5.4 Considerations for adjuvants in combination with biological products.

This section applies to the testing of proposed adjuvants on biological products containing living micro-organisms. Viruses are not classified as living organisms as these are dependent on living cells in order to replicate. However, considerations regarding viruses are included in this section (see 5.4.5 below).

5.4.1. Grouping of Living Micro-organisms

Biological products containing living micro-organisms can be divided into the following groups:

a) Rhizobia:
(e.g. *Rhizobium* spp., *Bradyrhizobium* spp*., Mesorhizobium* spp., *Sinorhizobium* spp., etc.)

b) Other gram negative bacteria:
(e.g. *Pseudomonas* spp*., Azospirillum* spp*., Azotobacter* spp., *Acetobacter* spp., etc.)

c) Gram positive bacteria:
(e.g. *Bacillus* spp., etc.)

d) Mycorrhizal fungi

e) Non-mycorrhizal fungi
(e.g. *Trichoderma* spp., *Beauveria* spp., etc.)

In order to register an adjuvant, it is of the utmost importance that the proposed adjuvant will not adversely affect the microbial active ingredient of a biological product. Therefore, compatibility tests must indicate that the biological function (e.g. viability, longevity and/or reproduction) of a microbial active ingredient is not reduced with the addition of a proposed adjuvant. This is the primary objective which is relevant for testing Class A and/or Class B adjuvants in combination with such products.

Most biological products with living micro-organisms contain vegetative cells (bacterial), spores (fungal or bacterial) and/or other propagation units (fungal). Therefore, ensure that the appropriate method be used during adjuvant/microbe compatibility tests.

5.4.2. Compatibility testing for adjuvants with microbes

The following methods may be used to conduct adjuvant/microbe compatibility:

a) **Colony forming unit (cfu) counts of product in packaging:**
Serial dilution of samples followed by plating onto specific growth media, depending on the organism tested, is the default method used. Counting chambers (e.g. Petroff Hauser, Neubauer, etc.) can be used to count individual cells or spores, but should still be correlated with cfu counts to determine viability.

b) **Stain techniques:**
These could be of use for mycorrhizal analysis. However, specialised equipment and training is needed for these methods.

c) **Testing of mycorrhizal products:**
To evaluate proposed adjuvant/mycorrhiza compatibility, a seed/petri dish method can be followed to determine microbe viability. The objective of the trial would be to combine the proposed adjuvant with the mycorrhiza product on seed (e.g. maize or wheat), let the seed develop in a growth agar (e.g. potato-dextrose agar (PDA) and inspect microbe viability on the developing root system, under a microscope.

The following techniques are not advised:

a) **Post application detection on seed/leaf by imprinting on a plate containing appropriated growth medium:**
Such trials may be affected by non-target organisms on the leaves or seeds, due to the samples not being sterile. Since contamination could be an issue, this method is not advised for adjuvant/microbe compatibility tests.

b) **MPN/Bio-assay:**
These methods require specialised equipment. If the assessment is conducted after application, contamination will be an issue in a non-sterile environment. Therefore, this method is not advised for adjuvant/microbe compatibility tests.

5.4.3. Compatibility testing for UV protectors and microbe supporters:

a) **Testing of UV protectors with microbes:**
Where adjuvants are proposed as UV protectors for microbial products, controlled trials are needed to indicate that the micro-organism is benefitted when applied with the adjuvant in the presence of UV radiation, compared to an untreated control. Conducting field trials will provide inaccurate results due to environmental and climatic conditions affecting levels of UV radiation present and general microbial performance in an open system. The Earth's atmosphere absorbs all shortwave and most medium wave UV radiation. Therefore, UV protector/microbial compatibility and efficacy must be evaluated at UVA frequencies of 315-400 nm since most of the UV spectrum that penetrates the atmosphere falls within this range. Black lights conforming to UVA frequency specifications may be used to conduct small-scale, controlled trials in which UV protector/microbe compatibility and efficacy at a specific set of time frames is tested to induce a viability gradient over time.

b) Products serving as promoters of microbial viability:

Proposed adjuvants providing microbe active ingredients with added protection, nutrients and/or any other enhancement of microbe viability over and above the standard formulation, must indicate under controlled conditions that the micro-organism is benefitted when applied in combination with such an adjuvant compared to an untreated control.

5.4.4. Further remarks on adjuvant/microbe compatibility testing:

- In most cases laboratory trials confirming adjuvant/microbe compatibility will be acceptable. Contamination of samples must be avoided at all cost. This is the main reason why controlled laboratory trials are preferred. In all cases, micro-organisms must be tested in combination with the proposed adjuvant for a specific set of time frames to induce a viability gradient over time. Time frames to be selected will be determined by indications as specified by labels from both adjuvant and biological products.

- In the case of Class A adjuvants requiring residue trials, it is not required that the biological product be tested in combination with the proposed adjuvant in field. Microbial products in general should not add to residue levels of proposed adjuvants. Testing for residues of adjuvants in combination with biological products is mandatory if the biological product has known residue characteristics.

- Viability of the micro-organism serving as active ingredient in a biological product must be the main focus of adjuvant/microbe compatibility trials, not adjuvant efficacy.

5.4.5. Considerations for compatibility of adjuvants with virus-containing products

Viruses are classified as non-living organisms as these are dependent on resources from living cells in order to replicate. It is, however, important to test proposed adjuvants in combination with biological products containing viruses as active ingredients.

Adjuvant/virus compatibility must be confirmed in the sense that no adverse effects occurs when combined. Trials must include a specific set of time frames to induce a viability gradient over time. Time frames to be selected will be determined by indications as specified by labels from both adjuvant and biological products. Small scale and controlled efficacy trials (laboratory or greenhouse) should be conducted to determine that the virus is efficacious against its target organism when combined with the proposed adjuvant.

6. Labelling requirements

The label of an adjuvant has to conform to the “Regulations relating to Agricultural Remedies” (Gov. Gaz. No 29225, 2006) (7) and the requirements of the "Guidelines for the RSA Classification Code of Agricultural and Stock Remedies and Associated Labelling Practices" (8). Where the remedy will also be marketed in a small pack for the home-garden market the proposed home-garden label should also be submitted. Refer to SANS Code 1268: “Labelling Practices for Agricultural Remedies and Fertilizers registered for Home and Home Garden Sector” issued by SABS, 22 November, 2013 (9).

In addition to these requirements, adjuvant labels should also contain the following information:

Label claims for any adjuvant to be registered should be made in terms of the adjuvant functional properties e.g. wetters, stickers, buffer or spreader etc. as defined in section 5. If the adjuvant performs more than one function, then each category should be specified on the label.

General statements indicating that an adjuvant is compatible with agricultural remedies (i.e. Fungicides, insecticide, herbicides, swimming pool products, botanical extracts, biological/biopesticide products, legume inoculants, plant growth regulators and fertilizers) are not acceptable. Compatibility may only be claimed with groups of agricultural remedies for which data has been submitted in accordance with section 5 above or which are approved as two third claims based on data submitted.

Adjuvant product labels should contain the following information in addition to the general labelling requirements of agricultural remedies:

Front panel:

- List the common chemical name according to IUPAC, ELINCS/EINECS and/or CAS nomenclature for each active constituent in the formulation that contributes to the adjuvant properties of the product and, where possible, the chemical group to which the active belongs.
- Specify the range or maximum possible concentration of each of these active constituents in g/kg for solid formulations and g/L for liquid formulations.
- Provide a product use declaration in which the adjuvant category should be stated (i.e. surfactant, oil, buffers etc.), the area of use as well as the formulation type of the product.

Side panel:

- The following statement must be included under Warnings, Use Restrictions and/or above the Recommendations table:

  PRODUCT Z SHOULD ONLY BE APPLIED IN TANK MIX WITH PESTICIDE GROUPS MENTIONED ON THIS LABEL. CONSIDERATION MUST BE GIVEN TO THE MAXIMUM RESIDUE LEVELS AND RECOMMENDED WITHHOLDING PERIODS OF SELECTED, REGISTERED TANK MIX PARTNER PRODUCTS.

- In the case that applications with the adjuvant will result in an extension of the approved withholding period of an agricultural remedy, the following statement must be included Warnings, Use Restrictions and/or above the Recommendations table:

  THE USE OF PRODUCT Z HAS BEEN SHOWN TO EXTEND THE BREAKDOWN OF ACTIVE INGREDIENTS IN TANK MIX PARTNER PRODUCTS. A MINIMUM OF __ DAYS SHOULD BE ADDED TO THE REGISTERED WITHHOLDING PERIODS OF TANK MIX PARTNER PRODUCTS TO ENSURE THAT MAXIMUM RESIDUE LEVELS ARE NOT EXCEEDED AT HARVEST.

- For adjuvants which are buffers or acidifiers (5.2.1) or salt adjuvants (5.2.1), the product label should include a warning to farmers to test their water quality regularly to ensure that the addition of such an adjuvant is definitely necessary.
- Just prior to “Directions for Use” heading, the heading “Adjuvant Classification” should be included. In this section, each active constituent with adjuvant properties should be classified as Class A and Class B (or both) and the claim of functionality should be

described in accordance with the terminology included in this guideline under section 5. If an active has more than one functional category, all relevant functions should be itemised. e.g Active X is a Class A surfactant with spreading properties. Active Y is a Class A sticker and also has properties of Class B by resulting in a reduction in drift. Statements such as 'blend of non-ionic surfactants' are not suitable. Alternatively, active ingredients may be listed in a table format with class type and adjuvant category.

Active	Class	Category
X	A	Surfactant
Y	A B	Sticker Drift retardant

Adjuvants registered prior to the implementation of these guidelines will be granted 5 years from the date of implementation of these guidelines to submit labels which are in line with these labelling requirements.

7. REFERENCES AND LIST OF REGULATORY DOCUMENTS

(1) Guidelines on the data and documents required for registration of agricultural remedies in South Africa, Registrar of Act 36 of 1947, 2015.
(2) Guidelines of the registration process for agricultural remedies, Registrar of Act 36 of 1947, 2015.
(3) Department of Health, South Africa, General requirements for toxicological assessments of agricultural and stock remedies.
(4) Guidelines for the registration of agricultural adjuvant products, Australian Pesticides and Veterinary Medicines Authority, 2009.
(5) Guidelines on equivalence of agricultural remedies, Registrar of Act 36 of 1947, 2000.
(6) Guidelines published by the Organization of Economic Co-operation and Development (OECD) http://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm.
(7) Regulations relating to Agricultural Remedies (Gov. Gaz. No. 29225, 22 Sept 2006).
(8) Guidelines for the RSA Classification Code of Agricultural and Stock Remedies and Associated Labelling Practices (Dept. of Agriculture & AVCASA, 1991).
(9) SANS Code 1268: Labelling Practices for Agricultural Remedies and Fertilizers registered for Home and Home Garden Sector Nov 2013 (SABS).
(10) Manual on Development and use of FAO and WHO Specifications for Pesticides, November 2010. (http://whqlibdoc.who.int/publications/2006/9251048576_eng_update3.pdf)
(11) FAO Specifications for Agricultural Pesticides (http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/lpe/lpe-b/en/)
(12) Guidelines for specifying the Shelf Life of Plant Protection Products, CropLife International, 2009 Technical Monogragh No 17. (https://croplife.org/wp-content/uploads/pdf_files/Technical-Monograph-17-2nd-edition-June-2009.pdf)
(13) Guidelines on residue study requirements for registration of agricultural remedies and setting of maximum residue levels in South Africa, Registrar of Act 36 of 1947, 2016.
(14) The WHO recommended classification of pesticides by hazard and guidelines to classification: 2009 (World Health Organisation, 2010).

(15) (http://www.pesticides.gov.uk/guidance/industries/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-adjuvants.htm.) UK Applicant Guide Adjuvants.
(16) US EPA, Pesticide Registration Manual: Chapter 1, Overview of requirements for pesticide registration and registration obligation.(http://www2.epa.gov/pesticide-registration/pesticide-registration-manual)
(17) CropLife South Africa, Protocol for scientific verification of quality and specifications of pesticides that have reached at two year shelf life, 2015.
(18) EPPO standard series PP1 (efficacy evaluation of plant protection products) (EPPO: http://pp1.epo.org/).
(19) Seed treatment guidelines, (http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Guidelines)
(20) United Nations Globally Harmonised System of Classification and Labelling of Chemicals (GHS); Part 3: Health Hazards, Chapter 3.1.3 (p. 112) – Classification Criteria for Mixtures; 2011.
20. IRAC, HRAC, FRAC,
http://www.irac-online.org/

http://www.frac.info/

http://weedscience.org/documents/showdocuments.aspx?DocumentID=1193

Annex 1

Known Allergenic substances:

1. Egg
2. Cow's milk
3. Crustaceans
4. Molluscs
5. Fish
6. Peanuts
7. Soybeans
8. Tree nuts
9. Significant cereals (defined below)
10. Ingredients derived from foodstuffs listed as 1 – 9 above.

"Significant cereal" means any one of the following cereals:

a) Wheat, meaning any species belonging to the genus Triticum, including varieties such as kamut (khorasan wheat) and spelt;
b) Rye, meaning any species belonging to the genus Secale;
c) Barley, meaning any species belonging to the genus Hordeum;
d) Oats; or
e) Crossbred hybrids of wheat, rye or barley (e.g., triticale, which is a cross between wheat and rye).