

**Active substance**

**DOCUMENT OCA**

**COMPLETENESS CHECK FORM**

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## Version history<sup>1</sup>

Date	Data points containing amendments or additions and brief description	Document identifier and version number
February 2018	Initial version	

<sup>1</sup> It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

## OCA Evaluation Form Active Substance

for use in checking that all test and study reports required in accordance with SANCO/11802 have been provided

Active Substance: Aluminium silicate

Applicant: Tessenderlo Group N.V.

Date: February 2018

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	<i>Data gap</i>
1	Identity of the active substance				
1.1	Applicant	yes			<input type="checkbox"/>
1.2	Producer	yes			<input type="checkbox"/>
1.3	Common name proposed or ISO-accepted and synonyms	yes			<input type="checkbox"/>
1.4	Chemical name (IUPAC and CA nomenclature)	yes			<input type="checkbox"/>
1.5	Producer's development code numbers	yes			<input type="checkbox"/>
1.6	CAS, EC and CIPAC numbers	yes			<input type="checkbox"/>
1.7	Molecular and structural formula, molar mass	yes			<input type="checkbox"/>
1.8	Method of manufacture (synthesis pathway) of the active substance	yes			<input type="checkbox"/>
1.9	Specification of purity of the active substance in g/kg	yes			<input type="checkbox"/>
1.10	Identity and content of additives (such as stabilisers) and impurities				
1.10.1	Additives	yes			<input type="checkbox"/>
1.10.2	Significant impurities	not relevant			<input type="checkbox"/>
1.10.3	Relevant impurities	not relevant			<input type="checkbox"/>
1.11	Analytical profile of batches	yes			<input type="checkbox"/>
2	Physical and chemical properties of the active substance				
2.1	Melting point and boiling point	yes			<input type="checkbox"/>
2.2	Vapour pressure and volatility	yes			<input type="checkbox"/>
2.3	Appearance (physical state, colour)	yes			<input type="checkbox"/>

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	<i>Data gap</i>
2.4	Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths, optical purity	yes			<input type="checkbox"/>
2.5	Solubility in water	yes			<input type="checkbox"/>
2.6	Solubility in organic solvents	yes			<input type="checkbox"/>
2.7	Partition coefficient n-octanol/water	yes			<input type="checkbox"/>
2.8	Dissociation in water	yes			<input type="checkbox"/>
2.9	Flammability and self-heating	yes			<input type="checkbox"/>
2.10	Flash point	yes			<input type="checkbox"/>
2.11	Explosive properties	yes			<input type="checkbox"/>
2.12	Surface tension	yes			<input type="checkbox"/>
2.13	Oxidising properties	yes			<input type="checkbox"/>
2.14	Other studies	yes			<input type="checkbox"/>
3	Further information on the active substance (function, mode of action, handling)				
3.1	Use of the active substance	yes			<input type="checkbox"/>
3.2	Function	yes			<input type="checkbox"/>
3.3	Effects on harmful organisms	yes			<input type="checkbox"/>
3.4	Fields of use envisaged	yes			<input type="checkbox"/>
3.5	Harmful organisms controlled and crops or products protected or treated	yes			<input type="checkbox"/>
3.6	Mode of action	yes			<input type="checkbox"/>
3.7	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies	yes			<input type="checkbox"/>
3.8	Methods and precautions concerning handling, storage transport or fire	yes			<input type="checkbox"/>
3.9	Procedures for destruction or decontamination	yes			<input type="checkbox"/>
3.10	Emergency measures in case of an accident	yes			<input type="checkbox"/>
4	Analytical methods				

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	<i>Data gap</i>
4	Introduction				
4.1	Methods used for the generation of pre-approval data	yes			<input type="checkbox"/>
4.1.1	Methods of the analysis of the active substance as manufactured	yes			<input type="checkbox"/>
4.1.2	Methods for risk assessment	yes			<input type="checkbox"/>
4.2	Methods for post-approval control and monitoring purposes	yes			<input type="checkbox"/>
5	Toxicological and toxicokinetic studies on the active substance				
5.1	Studies on absorption, distribution, excretion and metabolism in mammals				
5.1.1	Absorption, distribution, excretion and metabolism by oral route	yes			<input type="checkbox"/>
5.1.2	Absorption, distribution, excretion and metabolism by other routes	yes			<input type="checkbox"/>
5.2	Acute toxicity				
5.2.1	Oral	yes			<input type="checkbox"/>
5.2.2	Dermal	yes			<input type="checkbox"/>
5.2.3	Inhalation	yes			<input type="checkbox"/>
5.2.4	Skin irritation	yes			<input type="checkbox"/>
5.2.5	Eye irritation	yes			<input type="checkbox"/>
5.2.6	Skin sensitization	yes			<input type="checkbox"/>
5.2.7	Phototoxicity	yes			<input type="checkbox"/>
5.3	Short-term toxicity				
5.3.1	Oral 28-day study	yes			<input type="checkbox"/>
5.3.2	Oral 90-day study	yes			<input type="checkbox"/>
5.3.3	Other routes	yes			<input type="checkbox"/>
5.4	Genotoxicity				

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5.4.1	<i>In vitro</i> studies	yes			<input type="checkbox"/>
5.4.2	<i>In vivo</i> studies in somatic cells	yes			<input type="checkbox"/>
5.4.3	<i>In vivo</i> studies in germ cells	yes			<input type="checkbox"/>
5.5	Long-term toxicity and carcinogenicity	yes			<input type="checkbox"/>
5.6	Reproductive toxicity				
5.6.1	Generational studies	yes			<input type="checkbox"/>
5.6.2	Developmental toxicity studies	yes			<input type="checkbox"/>
5.7	Neurotoxicity				
5.7.1	Neurotoxicity studies in rodents	yes			<input type="checkbox"/>
5.7.2	Delayed polyneuropathy studies	yes			<input type="checkbox"/>
5.8	Other toxicological studies				
5.8.1	Toxicity studies of metabolites as referred to in the introduction	not relevant			<input type="checkbox"/>
5.8.2	Supplementary studies on the active substance	not relevant			<input type="checkbox"/>
5.8.3	Endocrine disrupting properties	yes			<input type="checkbox"/>
5.9	Medical data				
5.9.1	Medical surveillance on manufacturing plant personnel and monitoring studies	yes			<input type="checkbox"/>
5.9.2	Data collected on humans	yes			<input type="checkbox"/>
5.9.3	Direct observations	yes			<input type="checkbox"/>
5.9.4	Epidemiological studies	yes			<input type="checkbox"/>
5.9.5	Diagnosis of poisoning (determination of active substance, metabolites), specific signs of poisoning, clinical tests	not relevant			<input type="checkbox"/>
5.9.6	Proposed treatment: first aid measures, antidotes, medical treatment	yes			<input type="checkbox"/>
5.9.7	Expected effects of poisoning	not relevant			<input type="checkbox"/>
6	Metabolism and residues data				

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6.1	Storage stability of residues	not relevant			<input type="checkbox"/>
6.2.	Metabolism, distribution and expression of residues				
6.2.1	Plants	not relevant			<input type="checkbox"/>
6.2.2	Poultry	not relevant			<input type="checkbox"/>
6.2.3	Lactating ruminants	not relevant			<input type="checkbox"/>
6.2.4	Pigs	not relevant			<input type="checkbox"/>
6.2.5	Fish	not relevant			<input type="checkbox"/>
6.3	Magnitude of residue trials in plants	not relevant			<input type="checkbox"/>
6.4	Feeding studies				
6.4.1	Poultry	not relevant			<input type="checkbox"/>
6.4.2	Ruminants	not relevant			<input type="checkbox"/>
6.4.3	Pigs	not relevant			<input type="checkbox"/>
6.4.4	Fish	not relevant			<input type="checkbox"/>
6.5	Effects of processing				
6.5.1	Nature of the residue	not relevant			<input type="checkbox"/>
6.5.2	Distribution of the residue in inedible peel/pulp	not relevant			<input type="checkbox"/>
6.5.3	Magnitude of residues in processed commodities	not relevant			<input type="checkbox"/>
6.6	Residues in rotational crops				
6.6.1	Metabolism in rotational crops	not relevant			<input type="checkbox"/>
6.6.2	Magnitude of residues in rotational crops	not relevant			<input type="checkbox"/>
6.7	Proposed residue definition and maximum residue levels				
6.7.1	Proposed residue definitions	not relevant			<input type="checkbox"/>
6.7.2	Proposed maximum residue levels (MRLs) and justification of the acceptability of the levels proposed	not relevant			<input type="checkbox"/>

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
6.7.3	Proposed maximum residue levels (MRLs) and justification of the acceptability of the levels proposed for imported products (import tolerances)	not relevant			<input type="checkbox"/>
6.8	Proposed safety intervals	not relevant			<input type="checkbox"/>
6.9	Estimation of the potential and actual exposure through diet and other sources	not relevant			<input type="checkbox"/>
6.10	Other studies	not relevant			<input type="checkbox"/>
6.10.1	Effect on the residue level in pollen and bee products	not relevant			<input type="checkbox"/>
7	Fate and behaviour in the environment				
7.1.1	Fat and behaviour in soil				
7.1.1.1	Aerobic degradation	yes			<input type="checkbox"/>
7.1.1.2	Anaerobic degradation	yes			<input type="checkbox"/>
7.1.1.3	Soil photolysis	yes			<input type="checkbox"/>
7.1.2	Rate of degradation in soil				
7.1.2.1	Laboratory studies				
7.1.2.1.1	Aerobic degradation of the active substance	yes			<input type="checkbox"/>
7.1.2.1.2	Aerobic degradation metabolites, breakdown and reaction products	yes			<input type="checkbox"/>
7.1.2.1.3	Anaerobic degradation of the active substance	yes			<input type="checkbox"/>
7.1.2.1.4	Anaerobic degradation of metabolites, breakdown and reaction products	yes			<input type="checkbox"/>
7.1.2.2	Field studies				
7.1.2.2.1	Soil dissipation studies	yes			<input type="checkbox"/>
7.1.2.2.2	Soil accumulation studies	yes			<input type="checkbox"/>
7.1.3	Adsorption and desorption in soil				
7.1.3.1	Adsorption and desorption				
7.1.3.1.1	Adsorption and desorption of the active substance	yes			<input type="checkbox"/>



SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	<i>Data gap</i>
7.1.3.1.2	Adsorption and desorption of metabolites, breakdown and reaction products	not relevant			<input type="checkbox"/>
7.1.3.2	Aged sorption	yes			<input type="checkbox"/>
7.1.4	Mobility in soil				
7.1.4.1	Column leaching studies				
7.1.4.1.1	Column leaching of the active substance	yes			<input type="checkbox"/>
7.1.4.1.2	Column leaching of metabolites, breakdown and reaction products	not relevant			<input type="checkbox"/>
7.1.4.2	Lysimeter studies	yes			<input type="checkbox"/>
7.1.4.3	Field leaching studies	yes			<input type="checkbox"/>
7.2	Fate and behaviour in water and sediment				
7.2.1	Route and rate of degradation in aquatic systems (chemical and photochemical degradation)				
7.2.1.1	Hydrolytic degradation	yes			<input type="checkbox"/>
7.2.1.2	Direct photochemical degradation	yes			<input type="checkbox"/>
7.2.1.3	Indirect photochemical degradation	yes			<input type="checkbox"/>
7.2.2	Route and rate of biological degradation in aquatic systems				
7.2.2.1	“Ready biodegradability”	yes			<input type="checkbox"/>
7.2.2.2	Aerobic mineralisation in surface water	yes			<input type="checkbox"/>
7.2.2.3	Water/sediment study	yes			<input type="checkbox"/>
7.2.2.4	Irradiated water/sediment study	yes			<input type="checkbox"/>
7.2.3	Degradation in the saturated zone	yes			<input type="checkbox"/>
7.3	Fate and behaviour in air				
7.3.1	Route and rate of degradation in air	yes			<input type="checkbox"/>
7.3.2	Transport via air	yes			<input type="checkbox"/>
7.3.3	Local and global effects	yes			<input type="checkbox"/>
7.4	Definition of the residue				

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7.4.1	Definition of the residue for risk assessment	not relevant			<input type="checkbox"/>
7.4.2	Definition of the residue for monitoring	not relevant			<input type="checkbox"/>
7.5	Monitoring data	not relevant			<input type="checkbox"/>
8	Ecotoxicological studies				
8.1	Effects on birds and other terrestrial vertebrates				
8.1.1	Effects on birds				
8.1.1.1	Acute oral toxicity to birds	yes			<input type="checkbox"/>
8.1.1.2	Short-term dietary toxicity to birds	yes			<input type="checkbox"/>
8.1.1.3	Sub-chronic toxicity and reproductive to birds	yes			<input type="checkbox"/>
8.1.2	Effects on terrestrial vertebrates other than birds				
8.1.2.1	Acute oral toxicity to mammals	yes			<input type="checkbox"/>
8.1.2.2	Long-term and reproductive toxicity to mammals	yes			<input type="checkbox"/>
8.1.3	Effects of active substance bioconcentration in prey of birds and mammals	yes			<input type="checkbox"/>
8.1.4	Effects on terrestrial vertebrate wildlife (birds, mammals, reptiles and amphibians)	yes			<input type="checkbox"/>
8.1.5	Endocrine disrupting properties	yes			<input type="checkbox"/>
8.2	Effects on aquatic organisms				
8.2.1	Acute toxicity to fish	yes			<input type="checkbox"/>
8.2.2	Long-term and chronic toxicity to fish				
8.2.2.1	Fish early life stage toxicity test	yes			<input type="checkbox"/>
8.2.2.2	Fish full life cycle test	yes			<input type="checkbox"/>
8.2.2.3	Bioconcentration in fish	not relevant			<input type="checkbox"/>
8.2.3	Endocrine disrupting properties	yes			<input type="checkbox"/>
8.2.4	Acute toxicity to aquatic invertebrates				
8.2.4.1	Acute toxicity to <i>Daphnia magna</i>	yes			<input type="checkbox"/>

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
8.2.4.2	Acute toxicity to an additional aquatic invertebrate species	not relevant			<input type="checkbox"/>
8.2.5	Long term and chronic toxicity to aquatic invertebrates				
8.2.5.1	Reproductive and development toxicity to <i>Daphnia magna</i>	no	MCA-9	not relevant	<input type="checkbox"/>
8.2.5.2	Reproductive and development toxicity to an additional aquatic invertebrate species	not relevant			<input type="checkbox"/>
8.2.5.3	Development and emergence in <i>Chironomus species</i>	not relevant			<input type="checkbox"/>
8.2.5.4	Sediment dwelling organisms	not relevant			<input type="checkbox"/>
8.2.6	Effects on algal growth				
8.2.6.1	Effects on growth of green algae	yes			<input type="checkbox"/>
8.2.6.2	Effects on growth of an additional algal species	not relevant			<input type="checkbox"/>
8.2.7	Effects on aquatic macrophytes	not relevant			<input type="checkbox"/>
8.2.8	Further testing on aquatic organisms	not relevant			<input type="checkbox"/>
8.3	Effects on arthropods				
8.3.1	Effects on bees				
8.3.1.1	Acute toxicity to bees				
8.3.1.1.1	Acute oral toxicity	yes			<input type="checkbox"/>
8.3.1.1.2	Acute contact toxicity	yes			<input type="checkbox"/>
8.3.1.2	Chronic toxicity to bees	yes			<input type="checkbox"/>
8.3.1.3	Effects on honeybees development and other honeybee life stages	no	MCA-9	Yes	<input type="checkbox"/>
8.3.1.4	Sub-lethal effects	yes			<input type="checkbox"/>
8.3.2	Effects on non-target arthropods other than bees	yes			<input type="checkbox"/>
8.3.2.1	Effects on <i>Aphidius rhopalosiphi</i>	yes			<input type="checkbox"/>
8.3.2.2	Effects on <i>Typhlodromus pyri</i>	yes			<input type="checkbox"/>
8.4	Effects on non-target soil meso- and macrofauna				

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8.4.1	Earthworm – sub-lethal effects	yes			<input type="checkbox"/>
8.4.2	Effects on non-target soil meso- and macrofauna (other than earthworms)	yes			<input type="checkbox"/>
8.4.2.1	Species level testing	yes			<input type="checkbox"/>
8.5	Effects on soil nitrogen transformation	yes			<input type="checkbox"/>
8.6	Effects on terrestrial non-target higher plants				
8.6.1	Summary of screening data	not relevant			<input type="checkbox"/>
8.6.2	Testing on non-target plants	not relevant			<input type="checkbox"/>
8.7	Effects on other terrestrial organisms (flora and fauna)	yes			<input type="checkbox"/>
8.8	Effects on biological methods for sewage treatment	yes			<input type="checkbox"/>
8.9	Monitoring data	yes			<input type="checkbox"/>
9	Literature data	yes			<input type="checkbox"/>
10	Classification and labelling	yes			<input type="checkbox"/>