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⁽¹⁾ Text with EEA relevance.

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2023/1753

of 11 September 2023

amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for pyriproxyfen in or on certain products*(Text with EEA relevance)*

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC ⁽¹⁾, and in particular Article 14(1), point (a), and Article 49(2) thereof,

Whereas:

- (1) Maximum residue levels ('MRLs') for pyriproxyfen were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) The European Food Safety Authority ('the Authority') submitted a reasoned opinion on the review of the existing MRLs for pyriproxyfen ⁽²⁾ in accordance with Article 12(1) of Regulation (EC) No 396/2005. The Authority recommended to lower the existing MRLs for pyriproxyfen on swine/bovine/goat/horse muscle, fat, liver and kidney, as well as in cattle/horse milk to the limit of determination ('LOD') in line with the principle of setting MRLs at levels as low as reasonably achievable and based on sufficient supporting data for the current good agricultural practices ('GAPs'). As there is no risk for consumers, it is appropriate to set the MRL for pyriproxyfen on these products in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.
- (3) The Authority further concluded that the MRLs for pyriproxyfen on almonds, chestnuts, hazelnuts, pecans, pistachios, walnuts, pine nuts kernels, pome fruits, grapes, table olives, kaki/Japanese persimmons, pineapples, tomatoes, sweet peppers, aubergines, cucurbits with edible peel, and watermelons should be lowered in line with the principle of setting MRLs at levels as low as reasonably achievable and based on the current GAPs and Codex maximum residue limits ('CXLs'), which are confirmed as being safe for consumers ⁽³⁾. It also concluded that the MRLs for pyriproxyfen on apricots, peaches, plums, strawberries, mangoes, papayas, melons, cotton seeds and tea should be maintained based on the current GAPs and CXLs, which are confirmed as being safe for consumers ⁽⁴⁾. In addition, the Authority concluded that the MRLs for pyriproxyfen on citrus fruits, cherries and kumquats should be raised based on the current GAPs and CXLs, which are confirmed as being safe for consumers. As the Authority

⁽¹⁾ OJ L 70, 16.3.2005, p. 1.

⁽²⁾ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for pyriproxyfen according to Article 12 of Regulation (EC) No 396/2005; *EFSA Journal* 2022;20(11):7617.

⁽³⁾ European Food Safety Authority; Scientific support for preparing an EU position in the 51st Session of the Codex Committee on Pesticide Residues (CCPR); *EFSA Journal* 2019;17(7):5797.

⁽⁴⁾ European Food Safety Authority; Scientific support for preparing an EU position for the 52nd Session of the Codex Committee on Pesticide Residues (CCPR); *EFSA Journal* 2021;19(8):6766.

confirmed in an earlier reasoned opinion ⁽⁵⁾ that the MRL for pyriproxyfen on banana is safe for consumers, that MRL can be maintained. However, as some information was not available, further consideration by risk managers was required. Therefore, while the MRLs for almonds, chestnuts, hazelnuts, pecans, pistachios, walnuts, pine nuts kernels, pome fruits, grapes, table olives, kaki/Japanese persimmons, pineapples, tomatoes, sweet peppers, aubergines, cucurbits with edible peel, watermelons, apricots, peaches, plums, strawberries, mangoes, papayas, melons, cotton seeds, tea, citrus fruits, cherries, kumquats and bananas are considered safe, they will be reviewed. The review will take into account the information available within two years from the publication of this Regulation. As there is no risk for consumers, it is appropriate to set the MRLs for pyriproxyfen on those products in Annex II to Regulation (EC) No 396/2005 at the levels identified by the Authority.

- (4) As the Authority identified that no residue trials were available to derive MRL values for pyriproxyfen on macadamias, avocados, granate apples/pomegranates, cherimoyas, potatoes, sweet potatoes and yams, other root and tuber vegetables except sugar beets, bulb vegetables, okra/lady's fingers, pumpkins, brassica vegetables (excluding brassica roots and brassica baby leaf crops), lettuces and salad plants, spinaches and similar leaves, watercresses, witloofs/Belgian endives, herbs and edible flowers, legume vegetables, stem vegetables, beans (dry), and soyabeans, further consideration by risk managers was required. In the absence of such trials, which are necessary to derive an MRL value, the Commission considers that it is appropriate to set the MRLs for those products at the product specific LODs set out in Annex II to Regulation (EC) No 396/2005.
- (5) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LODs. For pyriproxyfen, those laboratories proposed product specific LODs that are analytically achievable.
- (6) Through the World Trade Organisation, the trading partners of the Union were consulted on the new MRLs and their comments have been taken into account.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) To allow for the normal marketing, processing and consumption of products, this Regulation should not apply to products which have been produced in the Union or imported into the Union before the new MRLs become applicable and for which a high level of consumer protection is maintained. This is the case for all products.
- (9) A reasonable period should be allowed to elapse before the new MRLs become applicable, in order to permit Member States, third countries and food business operators to adapt themselves to the requirements which result from the modification of the MRLs.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II and III to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Article 2

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced in the Union or imported into the Union before 2 April 2024.

⁽⁵⁾ European Food Safety Authority; Reasoned Opinion on the modification of the existing maximum residue level for pyriproxyfen in bananas; *EFSA Journal* 2016;14(2):4387.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 2 April 2024.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes II and III to Regulation (EC) No 396/2005 are amended as follows:

(1) in Annex II, the following column for pyriproxyfen is added:

'ANNEX II

Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply ⁽¹⁾	Pyriproxyfen (F)
0100000	FRUITS, FRESH or FROZEN; TREE NUTS	
0110000	Citrus fruits	0,7
0110010	Grapefruits	(+)
0110020	Oranges	(+)
0110030	Lemons	(+)
0110040	Limes	(+)
0110050	Mandarins	(+)
0110990	Others (2)	
0120000	Tree nuts	0,01 (*)
0120010	Almonds	(+)
0120020	Brazil nuts	(+)
0120030	Cashew nuts	(+)
0120040	Chestnuts	(+)
0120050	Coconuts	(+)
0120060	Hazelnuts/cobnuts	(+)
0120070	Macadamias	
0120080	Pecans	(+)
0120090	Pine nut kernels	(+)
0120100	Pistachios	(+)
0120110	Walnuts	(+)
0120990	Others (2)	
0130000	Pome fruits	
0130010	Apples	0,05(+)
0130020	Pears	0,01 (*) (+)
0130030	Quinces	0,01 (*) (+)
0130040	Medlars	0,01 (*) (+)
0130050	Loquats/Japanese medlars	0,01 (*) (+)
0130990	Others (2)	0,01 (*)

0140000	Stone fruits	
0140010	Apricots	0,4(+)
0140020	Cherries (sweet)	1,5(+)
0140030	Peaches	0,5(+)
0140040	Plums	0,3(+)
0140990	Others (2)	0,01 (*)
0150000	Berries and small fruits	
0151000	(a) grapes	0,01 (*)
0151010	Table grapes	(+)
0151020	Wine grapes	(+)
0152000	(b) strawberries	0,05(+)
0153000	(c) cane fruits	0,01 (*)
0153010	Blackberries	
0153020	Dewberries	
0153030	Raspberries (red and yellow)	
0153990	Others (2)	
0154000	(d) other small fruits and berries	0,01 (*)
0154010	Blueberries	
0154020	Cranberries	
0154030	Currants (black, red and white)	
0154040	Gooseberries (green, red and yellow)	
0154050	Rose hips	
0154060	Mulberries (black and white)	
0154070	Azaroles/Mediterranean medlars	
0154080	Elderberries	
0154990	Others (2)	
0160000	Miscellaneous fruitswith	
0161000	(a) edible peel	
0161010	Dates	0,01 (*)
0161020	Figs	0,01 (*)
0161030	Table olives	0,01 (*) (+)
0161040	Kumquats	0,5(+)
0161050	Carambolas	0,01 (*)
0161060	Kaki/Japanese persimmons	0,01 (*) (+)
0161070	Jambuls/jambolans	0,01 (*)
0161990	Others (2)	0,01 (*)

0162000	(b) inedible peel, small	0,01 (*)
0162010	Kiwi fruits (green, red, yellow)	
0162020	Litchis/lychees	
0162030	Passionfruits/maracujas	
0162040	Prickly pears/cactus fruits	
0162050	Star apples/cainitos	
0162060	American persimmons/Virginia kaki	
0162990	Others (2)	
0163000	(c) inedible peel, large	
0163010	Avocados	0,01 (*)
0163020	Bananas	0,7(+)
0163030	Mangoes	0,02 (*) (+)
0163040	Papayas	0,3(+)
0163050	Granate apples/pomegranates	0,01 (*)
0163060	Cherimoyas	0,01 (*)
0163070	Guavas	0,01 (*)
0163080	Pineapples	0,01 (*) (+)
0163090	Breadfruits	0,01 (*)
0163100	Durians	0,01 (*)
0163110	Soursops/guanabanas	0,01 (*)
0163990	Others (2)	0,01 (*)
0200000	VEGETABLES, FRESH or FROZEN	
0210000	Root and tuber vegetables	0,01 (*)
0211000	(a) potatoes	
0212000	(b) tropical root and tuber vegetables	
0212010	Cassava roots/manioc	
0212020	Sweet potatoes	
0212030	Yams	
0212040	Arrowroots	
0212990	Others (2)	
0213000	(c) other root and tuber vegetables except sugar beets	
0213010	Beetroots	
0213020	Carrots	
0213030	Celeriacs/turnip rooted celeries	
0213040	Horseradishes	
0213050	Jerusalem artichokes	
0213060	Parsnips	

0213070	Parsley roots/Hamburg roots parsley	
0213080	Radishes	
0213090	Salsifies	
0213100	Swedes/rutabagas	
0213110	Turnips	
0213990	Others (2)	
0220000	Bulb vegetables	0,01 (*)
0220010	Garlic	
0220020	Onions	
0220030	Shallots	
0220040	Spring onions/green onions and Welsh onions	
0220990	Others (2)	
0230000	Fruiting vegetables	
0231000	(a) Solanaceae and Malvaceae	
0231010	Tomatoes	0,7(+)
0231020	Sweet peppers/bell peppers	0,6(+)
0231030	Aubergines/eggplants	0,6(+)
0231040	Okra/lady's fingers	0,01 (*)
0231990	Others (2)	0,01 (*)
0232000	(b) cucurbits with edible peel	0,04
0232010	Cucumbers	(+)
0232020	Gherkins	(+)
0232030	Courgettes	(+)
0232990	Others (2)	
0233000	(c) cucurbits with inedible peel	
0233010	Melons	0,07(+)
0233020	Pumpkins	0,01 (*)
0233030	Watermelons	0,02(+)
0233990	Others (2)	0,01 (*)
0234000	(d) sweet corn	0,01 (*)
0239000	(e) other fruiting vegetables	0,01 (*)
0240000	Brassica vegetables(excluding brassica roots and brassica baby leaf crops)	0,01 (*)
0241000	(a) flowering brassica	
0241010	Broccoli	
0241020	Cauliflowers	
0241990	Others (2)	

0242000	(b) head brassica	
0242010	Brussels sprouts	
0242020	Head cabbages	
0242990	Others (2)	
0243000	(c) leafy brassica	
0243010	Chinese cabbages/pe-tsai	
0243020	Kales	
0243990	Others (2)	
0244000	(d) kohlrabies	
0250000	Leaf vegetables, herbs and edible flowers	
0251000	(a) lettuces and salad plants	0,01 (*)
0251010	Lamb's lettuces/corn salads	
0251020	Lettuces	
0251030	Escaroles/broad-leaved endives	
0251040	Cresses and other sprouts and shoots	
0251050	Land cresses	
0251060	Roman rocket/rucola	
0251070	Red mustards	
0251080	Baby leaf crops (including brassica species)	
0251990	Others (2)	
0252000	(b) spinaches and similar leaves	0,01 (*)
0252010	Spinaches	
0252020	Purslanes	
0252030	Chards/beet leaves	
0252990	Others (2)	
0253000	(c) grape leaves and similar species	0,01 (*)
0254000	(d) watercresses	0,01 (*)
0255000	(e) witloofs/Belgian endives	0,01 (*)
0256000	(f) herbs and edible flowers	0,02 (*)
0256010	Chervil	
0256020	Chives	
0256030	Celery leaves	
0256040	Parsley	
0256050	Sage	
0256060	Rosemary	
0256070	Thyme	
0256080	Basil and edible flowers	

0256090	Laurel/bay leaves	
0256100	Tarragon	
0256990	Others (2)	
0260000	Legume vegetables	0,01 (*)
0260010	Beans (with pods)	
0260020	Beans (without pods)	
0260030	Peas (with pods)	
0260040	Peas (without pods)	
0260050	Lentils	
0260990	Others (2)	
0270000	Stem vegetables	0,01 (*)
0270010	Asparagus	
0270020	Cardoons	
0270030	Celeries	
0270040	Florence fennels	
0270050	Globe artichokes	
0270060	Leeks	
0270070	Rhubarbs	
0270080	Bamboo shoots	
0270090	Palm hearts	
0270990	Others (2)	
0280000	Fungi, mosses and lichens	0,01 (*)
0280010	Cultivated fungi	
0280020	Wild fungi	
0280990	Mosses and lichens	
0290000	Algae and prokaryotes organisms	0,01 (*)
0300000	PULSES	0,01 (*)
0300010	Beans	
0300020	Lentils	
0300030	Peas	
0300040	Lupins/lupini beans	
0300990	Others (2)	
0400000	OILSEEDS AND OIL FRUITS	
0401000	Oilseeds	
0401010	Linseeds	0,01 (*)
0401020	Peanuts/groundnuts	0,01 (*)
0401030	Poppy seeds	0,01 (*)

0401040	Sesame seeds	0,01 (*)
0401050	Sunflower seeds	0,01 (*)
0401060	Rapeseeds/canola seeds	0,01 (*)
0401070	Soyabeans	0,01 (*)
0401080	Mustard seeds	0,01 (*)
0401090	Cotton seeds	0,05(+)
0401100	Pumpkin seeds	0,01 (*)
0401110	Safflower seeds	0,01 (*)
0401120	Borage seeds	0,01 (*)
0401130	Gold of pleasure seeds	0,01 (*)
0401140	Hemp seeds	0,01 (*)
0401150	Castor beans	0,01 (*)
0401990	Others (2)	0,01 (*)
0402000	Oil fruits	0,01 (*)
0402010	Olives for oil production	(+)
0402020	Oil palms kernels	
0402030	Oil palms fruits	
0402040	Kapok	
0402990	Others (2)	
0500000	CEREALS	0,01 (*)
0500010	Barley	
0500020	Buckwheat and other pseudocereals	
0500030	Maize/corn	
0500040	Common millet/proso millet	
0500050	Oat	
0500060	Rice	
0500070	Rye	
0500080	Sorghum	
0500090	Wheat	
0500990	Others (2)	
0600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS	
0610000	Teas	15(+)
0620000	Coffee beans	0,05 (*)
0630000	Herbal infusions from	0,05 (*)

0631000	(a) flowers	
0631010	Chamomile	
0631020	Hibiscus/roselle	
0631030	Rose	
0631040	Jasmine	
0631050	Lime/linden	
0631990	Others (2)	
0632000	(b) leaves and herbs	
0632010	Strawberry	
0632020	Rooibos	
0632030	Mate/maté	
0632990	Others (2)	
0633000	(c) roots	
0633010	Valerian	
0633020	Ginseng	
0633990	Others (2)	
0639000	(d) any other parts of the plant	
0640000	Cocoa beans	0,05 (*)
0650000	Carobs/Saint John's breads	0,05 (*)
0700000	HOPS	0,05 (*)
0800000	SPICES	
0810000	Seed spices	0,05 (*)
0810010	Anise/aniseed	
0810020	Black caraway/black cumin	
0810030	Celery	
0810040	Coriander	
0810050	Cumin	
0810060	Dill	
0810070	Fennel	
0810080	Fenugreek	
0810090	Nutmeg	
0810990	Others (2)	
0820000	Fruit spices	0,05 (*)
0820010	Allspice/pimento	
0820020	Sichuan pepper	
0820030	Caraway	

0820040	Cardamom	
0820050	Juniper berry	
0820060	Peppercorn (black, green and white)	
0820070	Vanilla	
0820080	Tamarind	
0820990	Others (2)	
0830000	Bark spices	0,05 (*)
0830010	Cinnamon	
0830990	Others (2)	
0840000	Root and rhizome spices	
0840010	Liquorice	0,05 (*)
0840020	Ginger (10)	
0840030	Turmeric/curcuma	0,05 (*)
0840040	Horseradish (11)	
0840990	Others (2)	0,05 (*)
0850000	Bud spices	0,05 (*)
0850010	Cloves	
0850020	Capers	
0850990	Others (2)	
0860000	Flower pistil spices	0,05 (*)
0860010	Saffron	
0860990	Others (2)	
0870000	Aril spices	0,05 (*)
0870010	Mace	
0870990	Others (2)	
0900000	SUGAR PLANTS	0,01 (*)
0900010	Sugar beet roots	
0900020	Sugar canes	
0900030	Chicory roots	
0900990	Others (2)	
1000000	PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS	
1010000	Commodities from	0,01 (*)
1011000	(a) swine	
1011010	Muscle	
1011020	Fat	
1011030	Liver	

1011040	Kidney	
1011050	Edible offals (other than liver and kidney)	
1011990	Others (2)	
1012000	(b) bovine	
1012010	Muscle	
1012020	Fat	
1012030	Liver	
1012040	Kidney	
1012050	Edible offals (other than liver and kidney)	
1012990	Others (2)	
1013000	(c) sheep	
1013010	Muscle	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offals (other than liver and kidney)	
1013990	Others (2)	
1014000	d) goat	
1014010	Muscle	
1014020	Fat	
1014030	Liver	
1014040	Kidney	
1014050	Edible offals (other than liver and kidney)	
1014990	Others (2)	
1015000	(e) equine	
1015010	Muscle	
1015020	Fat	
1015030	Liver	
1015040	Kidney	
1015050	Edible offals (other than liver and kidney)	
1015990	Others (2)	
1016000	(f) poultry	
1016010	Muscle	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offals (other than liver and kidney)	
1016990	Others (2)	

1017000	(g) other farmed terrestrial animals	
1017010	Muscle	
1017020	Fat	
1017030	Liver	
1017040	Kidney	
1017050	Edible offals (other than liver and kidney)	
1017990	Others (2)	
1020000	Milk	0,01 (*)
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others (2)	
1030000	Birds eggs	0,01 (*)
1030010	Chicken	
1030020	Duck	
1030030	Geese	
1030040	Quail	
1030990	Others (2)	
1040000	Honey and other apiculture products (7)	0,05 (*)
1050000	Amphibians and Reptiles	0,01 (*)
1060000	Terrestrial invertebrate animals	0,01 (*)
1070000	Wild terrestrial vertebrate animals	0,01 (*)
1100000	PRODUCTS OF ANIMAL ORIGIN - FISH, FISHPRODUCTS AND ANY OTHER MARINE AND FRESHWATER FOOD PRODUCTS (8)	
1200000	PRODUCTS OR PART OF PRODUCTS EXCLUSIVELY USED FOR ANIMAL FEED PRODUCTION (8)	
1300000	PROCESSED FOOD PRODUCTS (9)	

(*) Indicates lower limit of analytical determination

(^a) For the complete list of products of plant and animal origin to which MRL's apply, reference should be made to Annex I

Pyriproxyfen (F)

(F) Fat soluble

The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 September 2025, or, if that information is not submitted by that date, the lack of it.

0110010 Grapefruits

0110020 Oranges

0110030 Lemons

0110040 Limes

0110050 Mandarins

0120010 Almonds
 0120020 Brazil nuts
 0120030 Cashew nuts
 0120040 Chestnuts
 0120050 Coconuts
 0120060 Hazelnuts/cobnuts
 0120080 Pecans
 0120090 Pine nut kernels
 0120100 Pistachios
 0120110 Walnuts
 0130020 Pears
 0130030 Quinces
 0130040 Medlars
 0130050 Loquats/Japanese medlars
 0140010 Apricots
 0140030 Peaches
 0151010 Table grapes
 0151020 Wine grapes
 0152000 (b) strawberries
 0161030 Table olives
 0161040 Kumquats
 0161060 Kaki/Japanese persimmons
 0163030 Mangoes
 0163040 Papayas
 0163080 Pineapples
 0231010 Tomatoes
 0231020 Sweet peppers/bell peppers
 0231030 Aubergines/eggplants
 0232010 Cucumbers
 0232020 Gherkins
 0232030 Courgettes
 0233010 Melons
 0401090 Cotton seeds
 0402010 Olives for oil production
 0610000 Teas

The European Food Safety Authority identified some information on residue trials and analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 September 2025, or, if that information is not submitted by that date, the lack of it.

0130010 Apples
 0140020 Cherries (sweet)
 0140040 Plums
 0163020 Bananas
 0233030 Watermelons'

(2) in Part A of Annex III, the column for pyriproxyfen is deleted.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1754**of 11 September 2023****correcting the German language version of Regulation (EU) No 965/2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 ⁽¹⁾, and in particular Article 31(1) thereof,

Whereas:

- (1) The German language version of Commission Regulation (EU) No 965/2012 ⁽²⁾ contains in Part ORO, Subpart FC, Section 1, point ORO.FC.100(c), of Annex III an error that affects the substance of that provision as regards the required licences and ratings.
- (2) The German language version of Regulation (EU) No 965/2012 should therefore be corrected accordingly. The other language versions are not affected.
- (3) The measures provided for in this Regulation are in accordance with the opinion of the committee established by Article 65(1) of Regulation (EC) No 216/2008 of the European Parliament and of the Council ⁽³⁾, delivered prior to the adoption of Regulation (EU) No 965/2012,

HAS ADOPTED THIS REGULATION:

*Article 1**(Does not concern the English language.)**Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 212, 22.8.2018, p. 1.

⁽²⁾ Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1).

⁽³⁾ Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.3.2008, p. 1).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1755**of 11 September 2023****renewing the approval of the low-risk active substance fat distillation residues in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 20(1) in conjunction with Article 22(1) thereof,

Whereas:

- (1) Commission Directive 2008/127/EC ⁽²⁾ included fat distillation residues as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (2) In accordance with Article 78(3) of Regulation (EC) No 1107/2009, active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾.
- (3) The approval of the active substance fat distillation residues, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 December 2024.
- (4) An application for the renewal of the approval of the active substance fat distillation residues was submitted to Czechia, the rapporteur Member State, and France, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ⁽⁵⁾ and within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossiers required to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority') in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be admissible by the rapporteur Member State.
- (6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the Authority and the Commission on 25 February 2021. In its draft renewal assessment report the rapporteur Member State proposed to renew the approval of fat distillation residues.
- (7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft renewal assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances (OJ L 344, 20.12.2008, p. 89).

⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

⁽⁵⁾ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

- (8) On 5 January 2023, the Authority communicated to the Commission its conclusion ⁽⁶⁾, according to which fat distillation residues can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Commission presented a renewal report and a draft Regulation regarding fat distillation residues to the Standing Committee on Plants, Animals, Food and Feed on 22 March 2023 and on 25 May 2023, respectively.
- (10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined and taken into consideration.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance fat distillation residues that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) The Commission further considers that fat distillation residues is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Fat distillation residues is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009.
- (13) It is therefore appropriate to renew the approval of fat distillation residues as a low-risk active substance.
- (14) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge and the outcome of the risk assessment, it is, however, necessary to set a minimum purity of fat distillation residues and a maximum amount of the impurity nickel in the fat distillation residues as manufactured in order to ensure the safety of the active substance when used in plant protection products.
- (15) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (16) Commission Implementing Regulation (EU) 2023/1446 ⁽⁷⁾ extended the approval period of fat distillation residues to 15 December 2024 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.
- (17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance fat distillation residues, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

⁽⁶⁾ Conclusion on the peer review of the pesticide risk assessment of the active substance fat distillation residues. *EFSA Journal* doi:10.2903/j.efsa.2023.7811.

⁽⁷⁾ Commission Implementing Regulation (EU) 2023/1446 of 12 July 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, calcium carbide, cymoxanil, dodemorph, ethylene, extract from tea tree, fat distillation residues, fatty acids C7-C20, flonicamid (IKI-220), gibberellic acid, gibberellins, halosulfuron-methyl, hydrolysed proteins, iron sulphate, magnesium phosphide, maltodextrin, metamitron, plant oils/clove oil, plant oils/rape seed oil, plant oils/spear mint oil, pyrethrins, sulcotrione, tebuconazole and urea (OJ L 178, 13.7.2023, p. 1).

*Article 2***Amendments to Implementing Regulation (EU) No 540/2011**

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II.

*Article 3***Entry into force and date of application**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 November 2023.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Fat distillation residues CAS No not available 915 (CIPAC No)	Not available	≥ 400 g/kg of cleaved fatty acids (free/ester bonded) palmitic acid min 19 % of cleaved fatty acids stearic acid min 18 % of cleaved fatty acids oleic acid min 37 % of cleaved fatty acids acid value min 70 mg KOH/g The following impurity is of toxicological concern and shall not exceed the following levels in the technical material: nickel max 0,1 g/kg	1 November 2023	31 October 2038	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on fat distillation residues, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate.

⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the renewal report.

ANNEX II

The Annex to Commission Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 229 on fat distillation residues is deleted;

(2) in Part D, the following entry is added:

No.	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'44	Fat distillation residues CAS No not available 915 (CIPAC No)	Not available	≥ 400 g/kg of cleaved fatty acids (free/ester bonded) palmitic acid min 19 % of cleaved fatty acids stearic acid min 18 % of cleaved fatty acids oleic acid min 37 % of cleaved fatty acids acid value min 70 mg KOH/g The following impurity is of toxicological concern and shall not exceed the following levels in the technical material: nickel max 0,1 g/kg	1 November 2023	31 October 2038	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on fat distillation residues, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate.

⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the renewal report.'

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1756**of 11 September 2023****renewing the approval of the low-risk active substance *Cydia pomonella* granulovirus (CpGV) in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) No 540/2011****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 20(1) in conjunction with Article 22(1) thereof,

Whereas:

- (1) Commission Directive 2008/113/EC ⁽²⁾ included *Cydia pomonella* granulovirus (CpGV) as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾.
- (3) The approval of the active substance *Cydia pomonella* granulovirus (CpGV), as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 August 2024.
- (4) An application for the renewal of the approval of the active substance *Cydia pomonella* granulovirus (CpGV) was submitted to Germany, the rapporteur Member State, and the Netherlands, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ⁽⁵⁾ and within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossiers required to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority') in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be admissible by the rapporteur Member State.
- (6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the Authority and the Commission on 16 October 2020. In its draft renewal assessment report the rapporteur Member State proposed to renew the approval of *Cydia pomonella* granulovirus (CpGV).
- (7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft renewal assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2008/113/EC of 8 December 2008 amending Council Directive 91/414/EEC to include several micro-organisms as active substances (OJ L 330, 9.12.2008, p. 6).

⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

⁽⁵⁾ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

- (8) On 4 October 2022, the Authority communicated to the Commission its conclusion ⁽⁶⁾ which indicated *Cydia pomonella* granulovirus (CpGV) can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Commission presented a renewal report and a draft of this Regulation regarding *Cydia pomonella* granulovirus (CpGV) to the Standing Committee on Plants, Animals, Food and Feed on 22 March 2023 and on 24 May 2023, respectively.
- (10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined and taken into consideration.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance *Cydia pomonella* granulovirus (CpGV) that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) The Commission further considers that *Cydia pomonella* granulovirus (CpGV) is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. *Cydia pomonella* granulovirus (CpGV) fulfils the conditions set out in point 5 of Annex II to Regulation (EC) No 1107/2009 as it belongs to the *Baculoviridae* family and has not demonstrated adverse effects on any non-target insects.
- (13) It is therefore appropriate to renew the approval of *Cydia pomonella* granulovirus (CpGV) as a low-risk substance.
- (14) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof, and in the light of current scientific and technical knowledge and the outcome of the risk assessment, it is, however, necessary to provide for certain conditions in order to ensure the fulfilment of the limits on relevant microbiological contamination and the protection of operators and workers, taking into account that microorganisms are *per se* considered as potential sensitizers.
- (15) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (16) Commission Implementing Regulation (EU) 2023/689 ⁽⁷⁾ extended the approval period of *Cydia pomonella* granulovirus (CpGV) to 15 August 2024 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.
- (17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽⁶⁾ EFSA (European Food Safety Authority), 2022. Peer review of the pesticide risk assessment of the active substance *Cydia pomonella* granulovirus (CpGV), *EFSA Journal* 2022;20(11):7630. Available online: www.efsa.europa.eu.

⁽⁷⁾ Commission Implementing Regulation (EU) 2023/689 of 20 March 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances *Bacillus subtilis* (Cohn 1872) strain QST 713, *Bacillus thuringiensis* subsp. Aizawai strains ABTS-1857 and GC-91, *Bacillus thuringiensis* subsp. Israeliensis (serotype H-14) strain AM65-52, *Bacillus thuringiensis* subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, *Beauveria bassiana* strains ATCC 74040 and GHA, clodinafop, *Cydia pomonella* Granulovirus (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, pyridaben, pyrimethanil, rimsulfuron, spinosad, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram (OJ L 91, 29.3.2023, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance *Cydia pomonella* granulovirus (CpGV), as specified in Annex I, is renewed, subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 November 2023.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 September 2023.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
<i>Cydia pomonella</i> granulovirus (CpGV)	Not applicable	<i>Bacillus cereus</i> : < 1×10 ⁷ CFU/g in the formulated products.	1 November 2023	31 October 2038	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Cydia pomonella</i> granulovirus (CpGV), and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁾, — the protection of operators and workers, taking into account that micro-organisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate.

⁽¹⁾ Further details on identity and specification of active substance are provided in the Review Report PLAN/2023/240.

⁽²⁾ https://ec.europa.eu/food/system/files/2016-10/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf.

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 198 on *Cydia pomonella* granulovirus (CpGV) is deleted;

(2) in Part D, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'45	<i>Cydia pomonella</i> granulovirus (CpGV)	Not applicable	<i>Bacillus cereus</i> : < 1 × 10 ⁷ CFU/g in the formulated products.	1 November 2023	31 October 2038	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Cydia pomonella</i> granulovirus (CpGV), and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁾, — the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate.

⁽¹⁾ Further details on identity and specification of active substance are provided in the Review Report PLAN/2023/240.

⁽²⁾ https://ec.europa.eu/food/system/files/2016-10/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1757

of 11 September 2023

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances bensulfuron, chlormequat, chlorotoluron, clomazone, daminozide, deltamethrin, eugenol, fludioxonil, flufenacet, flumetralin, fosthiazate, geraniol, MCPA, MCPB, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulfuryl fluoride, tebufenpyrad, thymol, and tritosulfuron

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 17, first paragraph, thereof,

Whereas:

- (1) According to Article 78(3) of Regulation (EC) No 1107/2009, active substances included in Annex I to Council Directive 91/414/EEC ⁽²⁾ are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽³⁾. Active substances approved under Regulation (EC) No 1107/2009 are listed in Part B of the Annex to Implementing Regulation (EU) No 540/2011, and active substances approved under Regulation (EC) No 1107/2009 as candidates for substitution are listed in Part E of that Annex.
- (2) The active substances bensulfuron, chlormequat, chlorotoluron, clomazone, daminozide, deltamethrin, fludioxonil, flufenacet, fosthiazate, MCPA, MCPB, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulfuryl fluoride, tebufenpyrad and tritosulfuron are listed in Part A of the Annex to Implementing Regulation (EU) No 540/2011. The active substances eugenol, geraniol and thymol are listed in Part B and the active substance flumetralin in Part E of that Annex.
- (3) Commission Implementing Regulation (EU) 2022/1480 ⁽⁴⁾ extended the approval period of the active substances bensulfuron, chlorotoluron, clomazone, daminozide, deltamethrin, fludioxonil, flufenacet, fosthiazate, MCPA, MCPB, prosulfocarb, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, and tebufenpyrad until 31 October 2023, of the active substances chlormequat, propaquizafop, quizalofop-P-ethyl, quizalofop-P-tefuryl and tritosulfuron until 30 November 2023 and of the active substance flumetralin until 11 December 2023.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽³⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) 2022/1480 of 7 September 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bensulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, esfenvalerate, etofenprox, fenoxaprop-P, fenpropidin, fenpyrazamine, fludioxonil, flufenacet, flumetralin, fosthiazate, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, prohexadione, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulphur, tebufenpyrad, tetraconazole, tri-allate, triflusaluron and tritosulfuron (OJ L 233, 8.9.2022, p. 43).

- (4) Commission Implementing Regulation (EU) 2018/184 ⁽⁵⁾ extended the approval period of the active substance sulfuryl fluoride until 31 October 2023.
- (5) The approval of the active substance eugenol is set to expire on 30 November 2023 in accordance with Commission Implementing Regulation (EU) No 546/2013 ⁽⁶⁾.
- (6) The approval of the active substance geraniol is set to expire on 30 November 2023 in accordance with Commission Implementing Regulation (EU) No 570/2013 ⁽⁷⁾.
- (7) The approval of the active substance thymol is set to expire on 30 November 2023 in accordance with Commission Implementing Regulation (EU) No 568/2013 ⁽⁸⁾.
- (8) Applications and supplementary dossiers for the renewal of the approval of each of those active substances were submitted in accordance with Commission Implementing Regulation (EU) No 844/2012 ⁽⁹⁾. All of these applications were declared admissible by the respective rapporteur Member States.
- (9) For the active substances chlormequat, eugenol, flumetralin, fosthiazate, geraniol, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulfuryl fluoride, tebufenpyrad and thymol, the risk assessment pursuant to Article 11 of Implementing Regulation (EU) No 844/2012 has not yet been finalised by the respective rapporteur Member States.
- (10) For the active substances bensulfuron, chlorotoluron, deltamethrin, MCPA and MCPB, the European Food Safety Authority ('the Authority') needs additional time to reach a conclusion requiring, where appropriate, a consultation of experts. Furthermore, additional time is needed for the Commission to adopt the ensuing risk management decision.
- (11) For the active substances clomazone, daminozide, fludioxonil, flufenacet and tritosulfuron, additional information for the purposes of assessment of the approval criteria set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, was requested by the Authority pursuant to Article 13(3a), first subparagraph, of Implementing Regulation (EU) No 844/2012 and was submitted by the applicants within the period set by the Authority. However, additional time is needed for the Authority to evaluate the information received and adopt a conclusion on whether the active substances can be expected to meet the approval criteria and for the Commission to adopt the ensuing risk management decision.

⁽⁵⁾ Commission Implementing Regulation (EU) 2018/184 of 7 February 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances FEN 560 (also called fenugreek or fenugreek seed powder) and sulfuryl fluoride (OJ L 34, 8.2.2018, p. 10).

⁽⁶⁾ Commission Implementing Regulation (EU) No 546/2013 of 14 June 2013 approving the active substance eugenol, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 163, 15.6.2013, p. 17).

⁽⁷⁾ Commission Implementing Regulation (EU) No 570/2013 of 17 June 2013 approving the active substance geraniol, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (OJ L 168, 20.6.2013, p. 18).

⁽⁸⁾ Commission Implementing Regulation (EU) No 568/2013 of 18 June 2013 approving the active substance thymol, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 167, 19.6.2013, p. 33).

⁽⁹⁾ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26), which continues to apply to the procedure for the renewal of the approval of those active substances pursuant to Article 17 of Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012 (OJ L 392, 23.11.2020, p. 20).

- (12) Given that it is likely that no decision on the renewal of the approval of these active substances can be taken before the expiry of their respective approval periods on 31 October 2023, 30 November 2023 and 11 December 2023, and that the reasons for the delays in the renewal procedures are beyond the control of the respective applicants, the approval periods of the active substances should be extended in order to enable the completion of the assessments required and finalise the regulatory decision-making procedures on the respective applications for renewal of approval.
- (13) As the risk assessment has not yet been finalised by the rapporteur Member States, and in light of the time required to complete the remaining steps in each renewal procedure, the duration of the extension for the active substances chlormequat, fosthiazate, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulfuryl fluoride and tebufenpyrad should be set at thirty-nine months and for the active substances eugenol, flumetralin, geraniol and thymol should be set at twenty-nine months.
- (14) As the Authority needs additional time to reach a conclusion on the risk assessment for the active substances bensulfuron, chlorotoluron, deltamethrin, MCPA and MCPB requiring, where appropriate, a consultation of experts, the duration of the extension for those active substances should be set at thirty-three months and a half.
- (15) As the Authority requested additional information for the purposes of assessment of the approval criteria set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, the duration of the extension for the active substance daminozide should be set at twenty-two months and a half and, as additional time is needed for its evaluation, the duration of the extension for the active substances clomazone, fludioxonil, flufenacet and tritosulfuron should be set at nineteen months and a half.
- (16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (17) In case the Commission adopts a Regulation providing that the approval of an active substance referred to in the Annex to this Regulation is not renewed, the Commission will set the expiry date at the same date as it stood before the adoption of this Regulation or at the date of the entry into force of the Regulation providing that the approval of the active substance is not renewed, whichever date is later. As regards cases where the Commission is to adopt a Regulation providing for the renewal of the approval of an active substance referred to in the Annex to this Regulation, the Commission will set, as appropriate under the circumstances, the earliest possible application date.
- (18) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

1. Part A is amended as follows:

- (1) in the sixth column, expiration of approval, of row 40, Deltamethrin, the date is replaced by '15 August 2026';
- (2) in the sixth column, expiration of approval, of row 65, Flufenacet, the date is replaced by '15 June 2025';
- (3) in the sixth column, expiration of approval, of row 69, Fosthiazate, the date is replaced by '31 January 2027';
- (4) in the sixth column, expiration of approval, of row 102, Chlorotoluron, the date is replaced by '15 August 2026';
- (5) in the sixth column, expiration of approval, of row 104, Daminozide, the date is replaced by '15 September 2025';
- (6) in the sixth column, expiration of approval, of row 107, MCPA, the date is replaced by '15 August 2026';
- (7) in the sixth column, expiration of approval, of row 108, MCPB, the date is replaced by '15 August 2026';
- (8) in the sixth column, expiration of approval, of row 160, Prosulfocarb, the date is replaced by '31 January 2027';
- (9) in the sixth column, expiration of approval, of row 161, Fludioxonil, the date is replaced by '15 June 2025';
- (10) in the sixth column, expiration of approval, of row 162, Clomazone, the date is replaced by '15 June 2025';
- (11) in the sixth column, expiration of approval, of row 186, Tritosulfuron, the date is replaced by '15 July 2025';
- (12) in the sixth column, expiration of approval, of row 271, Bensulfuron, the date is replaced by '15 August 2026';
- (13) in the sixth column, expiration of approval, of row 272, Sodium 5-nitroguaiacolate, the date is replaced by '31 January 2027';
- (14) in the sixth column, expiration of approval, of row 273, Sodium o-nitrophenolate, the date is replaced by '31 January 2027';
- (15) in the sixth column, expiration of approval, of row 274, Sodium p-nitrophenolate, the date is replaced by '31 January 2027';
- (16) in the sixth column, expiration of approval, of row 275, Tebufenpyrad, the date is replaced by '31 January 2027';
- (17) in the sixth column, expiration of approval, of row 276, Chlormequat, the date is replaced by '28 February 2027';
- (18) in the sixth column, expiration of approval, of row 278, Propaquizafop, the date is replaced by '28 February 2027';
- (19) in the sixth column, expiration of approval, of row 279, Quizalofop-P-ethyl and Quizalofop-P-tefuryl, the date is replaced by '28 February 2027';
- (20) in the sixth column, expiration of approval, of row 307, Sulfuryl fluoride, the date is replaced by '31 January 2027'.

2. Part B is amended as follows:
 - (1) in the sixth column, expiration of approval, of row 45, Eugenol, the date is replaced by '30 April 2026';
 - (2) in the sixth column, expiration of approval, of row 46, Geraniol, the date is replaced by '30 April 2026';
 - (3) in the sixth column, expiration of approval, of row 47, Thymol, the date is replaced by '30 April 2026';
 3. Part E is amended as follows:

in the sixth column, expiration of approval, of row 1, Flumetralin, the date is replaced by '11 May 2026'.
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COMMISSION IMPLEMENTING REGULATION (EU) 2023/1758**of 11 September 2023****granting a Union authorisation for the biocidal product family ‘SALVECO SALVESAFE PRODUCTS’
in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 26 April 2019, Salveco SAS submitted to the European Chemicals Agency (‘the Agency’) an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for a Union authorisation of a biocidal product family named ‘SALVECO SALVESAFE PRODUCTS’ of product-types 2, 3 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of France had agreed to evaluate the application. The application was recorded under case number BC-HC051278-51 in the Register for Biocidal Products.
- (2) ‘SALVECO SALVESAFE PRODUCTS’ contains L-(+)-lactic acid as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 2, 3 and 4.
- (3) On 7 January 2022, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.
- (4) On 5 July 2022, the Agency submitted to the Commission its opinion ⁽²⁾, the draft summary of the biocidal product characteristics (‘SPC’) of ‘SALVECO SALVESAFE PRODUCTS’ and the final assessment report on the biocidal product family, in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that ‘SALVECO SALVESAFE PRODUCTS’ is a biocidal product family within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (6) On 20 July 2022, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the biocidal product family ‘SALVECO SALVESAFE PRODUCTS’.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 15 June 2022 on the Union authorisation of ‘SALVECO SALVESAFE PRODUCTS’ (ECHA/BPC/346/2022), <https://echa.europa.eu/opinions-on-union-authorisation>.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0028967-0000 is hereby granted to Salvco SAS for the making available on the market and use of the biocidal product family 'SALVECO SALVESAFE PRODUCTS' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 2 October 2023 to 30 September 2033.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT FAMILY

SALVECO SALVESAFE PRODUCTS

Product type 2 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)

Product type 3 - Veterinary hygiene (Disinfectants)

Product type 4 - Food and feed area (Disinfectants)

Authorisation number: EU-0028967-0000

R4BP asset number: EU-0028967-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	SALVECO SALVESAFE PRODUCTS
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1.2. Product type(s)

Product type(s)	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT03 - Veterinary hygiene (Disinfectants) PT04 - Food and feed area (Disinfectants)
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1.3. Authorisation holder

Name and address of the authorisation holder	Name	SALVECO S.A.S.
	Address	Avenue Pierre Mendès-France Z.A. Hellieule 4, F 88100 SAINT DIE DES VOSGES France
Authorisation number	EU-0028967-0000	
R4BP asset number	EU-0028967-0000	
Date of the authorisation	2 October 2023	
Expiry date of the authorisation	30 September 2033	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	SALVECO S.A.S
Address of manufacturer	Avenue Pierre Mendès-France, F-88100 SAINT DIE DES VOSGES France
Location of manufacturing sites	Avenue Pierre Mendès-France, F-88100 SAINT DIE DES VOSGES France

Name of manufacturer	GESTRA S.A.S
Address of manufacturer	Allée Robert Schumann, F-88110 RAON-L'ETAPE France
Location of manufacturing sites	Allée Robert Schumann, F-88110 RAON-L'ETAPE France

1.5. Manufacturer(s) of the active substance(s)

Active substance	L-(+)-lactic acid
Name of manufacturer	PURAC BIOCHEM BV
Address of manufacturer	Gran Vial 19-25, 08160 Montmelo Spain
Location of manufacturing sites	Gran Vial 19-25, 08160 Montmelo Spain

Active substance	L-(+)-lactic acid
Name of manufacturer	JUNGBUNZLAUER S.A
Address of manufacturer	Z.I Portuaire BP 32, 67390 Marckolsheim France
Location of manufacturing sites	Z.I Portuaire BP 32, 67390 Marckolsheim France

2. PRODUCT FAMILY COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	0,627	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		0,0	28,8
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		0,0	8,23

2.2. Type(s) of formulation

Formulation(s)	SL – Soluble Concentrate AL – Any other liquids
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PART II

SECOND INFORMATION LEVEL - META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	meta-SPC1
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1.2. Suffix to the authorisation number

Number	1-1
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1.3. Product type(s)

Product type(s)	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
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2. META SPC 1 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	15,66	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		13,5	27,0
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		3,52	8,23

2.2. Type(s) of formulation of the meta SPC 1

Formulation(s)	SL – Soluble Concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Causes skin irritation. Causes serious eye damage.
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Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Read carefully and follow all instructions. Wash hands thoroughly after handling. Wear protective gloves, protective clothing and eye protection. IF ON SKIN:Wash with plenty of water. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor. Specific treatment (see supplemental first aid instruction on this label). If skin irritation occurs:Get medical advice. Take off contaminated clothing.And wash it before reuse.
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4. AUTHORISED USE(S) OF THE META SPC 1

4.1. Use description

Table 1

Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in domestic, institutional, medical and industrial areas)

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage: Scientific name: Viruses Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor Outdoor In domestic, institutional, medical and industrial areas
Application method(s)	Method: Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): 0,299% to 1,496%

	Number and timing of application: Mandatory target organisms: — Bacteria: 0,299% to 1,496% w/w L-(+)-lactic acid, 5 minutes, 20°C Other target organisms: — Enveloped viruses and yeasts: 0,299% to 1,496% w/w L-(+)-lactic acid, 5 minutes, 20°C Minimum in use concentration of surfactants shall be 0,29% for any future product included in this meta SPC.
Category(ies) of users	Professional General public (non-professional)
Pack sizes and packaging material	Package size for non-professional is restricted to maximum 3 liters and packaging above 1 liter should be equipped with a handle Refill caps: 20 - 100ml high density polyethylene (HDPE) Bottles: 0,5 - 5 liters HDPE or polyethylene terephthalate (PET) Jerry can: 1-80 liters HDPE (only for professional users) Drum: 10-210 liters HDPE (only for professional users) Intermediate bulk container (IBC): 1 000 liters HDPE (only for professional users)

4.1.1. *Use-specific instructions for use*

See general instructions for use.

4.1.2. *Use-specific risk mitigation measures*

See general instructions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use.

4.2. Use description

Table 2

Use # 2 – Food and feed area disinfectants (disinfectant for all washable hard surfaces in domestic, institutional and food industry areas)

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage:
Field(s) of use	Indoor Outdoor — in domestic, institutional and food industry areas (general disinfection)
Application method(s)	Method: Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): 0,299% to 1,496% Number and timing of application: Mandatory target organisms: — Bacteria and yeast: 0,299% to 1,496% w/w L-(+)-lactic acid, 5 minutes, 20°C Minimum in use concentration of surfactants shall be 0,29% for any future product included in this meta SPC.
Category(ies) of users	Professional General public (non-professional)
Pack sizes and packaging material	Package size for non-professional is restricted to maximum 3 liters and packaging above 1 liter should be equipped with a handle Refill caps: 20 - 100ml high density polyethylene (HDPE) Bottles: 0,5 - 5 liters HDPE or polyethylene terephthalate (PET) Jerry can: 1-80 liters HDPE (only for professional users) Drum: 10-210 liters HDPE (only for professional users) Intermediate bulk container (IBC): 1 000 liters HDPE (only for professional users)

4.2.1. *Use-specific instructions for use*

See general instructions for use.

4.2.2. *Use-specific risk mitigation measures*

See general instructions for use.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use.

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use.

5. **GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 1**5.1. **Instructions for use**

- Apply the product by fully wetting all surface for 5 minutes (apply approx. 18 sprays /m² or 20 ml/m² or fully cover the object to be disinfected).
- Apply only on non-porous surfaces.
- Inform the authorisation holder if the treatment is ineffective.
- Comply with the instructions for use.
- Each product label shall give information on how the dilution should be made in order to guarantee the efficacy of the product. Since the concentration of L-(+)-lactic acid in products within this meta SPC can range from 15,66% to 31,33%, it is not possible to indicate all product dilution here.

Example for a product containing 15,66% L-(+)-lactic acid	Dilution of the product	Contact time
Bacterial and yeasticidal activity	0,299% (20 ml product, add water up to 1 liter)	5 minutes

The authorisation holder shall indicate on the label the relevant volume of product to be diluted in water for each specific product.

5.2. **Risk mitigation measures**

- Wash hands after use of the concentrate product.
- Avoid contact with eyes.
- Avoid splashes and spills during mixing and loading (dilution).
- For outdoor uses, do not apply the product in case rain is expected within 24 hours.
- For outdoor uses by spray, avoid transfer to other areas by wind (drift).

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

For professional use only:

- Wear protective chemical resistant gloves classified under EN 374 or equivalent, chemical goggles consistent with EN 16321 or equivalent and a coverall consistent with EN 14605 or equivalent when handling the concentrate product (during dilution). The full texts of the EN standards are available in Section 6. – Personal protective equipment (PPE) material to be specified by the authorisation holder within the product information.

For non-professional use only:

- A child-proof closure is required.
- Keep out of reach of children and non-target animals or pets.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- If medical advice is needed, have product container or label at hand
- IF ON SKIN: take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.
- IF IN EYES: immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.

Call 112 or an ambulance for medical assistance.

Information to healthcare personnel or a doctor:

The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

- IF SWALLOWED: immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.
- IF INHALED: if symptoms occur call a POISON CENTRE or a doctor.

5.4. Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

- Keep out of reach of children and non-target animals or pets.
- Shelf-life: 2 years.
- Protect from frost.

6. OTHER INFORMATION

- P280 (Wear protective gloves/protective clothing/eye protection/face protection) is not applicable for the non-professional user.

The full titles of the EN standards referenced in section 5.2 "Risk mitigation measures" are:

EN 374 - Protective gloves against dangerous chemicals and micro-organisms

EN 16321 - Eye and face protection for occupational use

EN 14605 - Protective clothing against liquid chemicals - Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM1_1		Market area: EU		
Authorisation number	EU-0028967-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		27,0
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		8,23

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM1_5		Market area: EU		
Authorisation number	EU-0028967-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	20,89
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		18,0
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		5,49

7.3. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM1_9		Market area: EU		
	OSANIS – Nettoyant désinfectant concentré		Market area: EU		
Authorisation number	EU-0028967-0003 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	15,66

Sodium octyl ether carboxylate		Non-active substance	53563-70-5		13,5
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		4,11

7.4. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM1_13		Market area: EU		
	MILTON - Dégraissant désinfectant		Market area: EU		
Authorisation number	EU-0028967-0004 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		27,0
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		3,52

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	meta-SPC2
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

Product type(s)	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
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2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	15,66	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		13,5	27,0
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		3,52	8,23

2.2. Type(s) of formulation of the meta SPC 2

Formulation(s)	SL – Soluble Concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Causes skin irritation. Causes serious eye damage. Contains Eucalyptol, Carvone and Limonene. May produce an allergic reaction. Contains Methyl salicylate and Eugenol (Pure fragrance). May produce an allergic reaction. Contains Eucalyptol (Eucalyptus leaves fragrance). May produce an allergic reaction.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Read carefully and follow all instructions. Wash hands thoroughly after handling. Wear protective gloves, protective clothing and eye protection. IF ON SKIN: Wash with plenty of water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor. Specific treatment (see supplemental first aid instruction on this label). If skin irritation occurs: Get medical advice. Take off contaminated clothing. And wash it before reuse.

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. Use description

Table 3

Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in domestic, institutional, medical and industrial areas)

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage: Scientific name: Viruses Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor Outdoor in domestic, institutional, medical and industrial area.
Application method(s)	Method: Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping Detailed description: — without mechanical action.
Application rate(s) and frequency	Application Rate: - Dilution (%): 0,299% to 1,496% Number and timing of application: Mandatory target organisms: — Bacteria: 0,299% to 1,496% w/w L-(+)-lactic acid, 5 minutes, 20°C Other target organisms: — Enveloped viruses and yeasts: 0,299% to 1,496% w/w L-(+)-lactic acid, 5 minutes, 20°C Minimum in use concentration of surfactants shall be 0,29% for any future product included in this meta SPC.
Category(ies) of users	Professional General public (non-professional)

Pack sizes and packaging material	Package size for non-professional is restricted to maximum 3 liters and packaging above 1 liter should be equipped with a handle Refill caps: 20 - 100 ml HDPE Bottles: 0,5 - 5 liters HDPE or PET Jerry can: 1-80 liters HDPE (only for professional users) Drum: 10-210 liters HDPE (only for professional users) IBC: 1 000 liters HDPE (only for professional users)
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4.1.1. *Use-specific instructions for use*

See general instructions for use

4.1.2. *Use-specific risk mitigation measures*

See general instructions for use

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use

4.2. **Use description**

Table 4

Use # 2 – Food and feed area disinfectants (disinfectant for all washable hard surfaces in domestic, institutional and food industry areas)

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage:
Field(s) of use	Indoor Outdoor — in domestic, institutional and food industry areas (general disinfection)

Application method(s)	Method: Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): 0,299% to 1,496% Number and timing of application: Mandatory target organisms: — Bacteria and yeast: 0,299% to 1,496% w/w L-(+)-lactic acid, 5 minutes, 20°C Minimum in use concentration of surfactants shall be 0,29% for any future product included in this meta SPC.
Category(ies) of users	Professional General public (non-professional)
Pack sizes and packaging material	Package size for non-professional is restricted to maximum 3 liters and packaging above 1 liter should be equipped with a handle Refill caps: 20 - 100ml HDPE Bottles: 0,5 - 5 liters HDPE or PET Jerry can: 1-80 liters HDPE (only for professional users) Drum: 10-210 liters HDPE (only for professional users) IBC: 1 000 liters HDPE (only for professional users)

4.2.1. *Use-specific instructions for use*

See general instructions for use

4.2.2. *Use-specific risk mitigation measures*

See general instructions for use

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use

5. GENERAL DIRECTIONS FOR USE ^(?) OF THE META SPC 2

5.1. Instructions for use

- Apply the product by fully wetting all surface for 5 minutes (apply approx. 18 sprays /m² or 20 ml/m² or fully cover the object to be disinfected).
- Apply only on non porous surfaces.
- Inform the authorisation holder if the treatment is ineffective.
- Comply with the instructions for use.
- Each product label shall give information on how the dilution should be made in order to guarantee the efficacy of the product. Since the concentration of L-(+)-lactic acid in products within this meta SPC can range from 15,66% to 31,33%, it is not possible to indicate all product dilution here.

Example for a product containing 15,66% L-(+)-lactic acid	Dilution of the product	Contact time
Bacterial and yeasticidal activity	0,299% (20 ml product, add water up to 1 liter)	5 minutes

The authorisation holder shall indicate on the label the relevant volume of product to be diluted in water on the label of each specific product.

5.2. Risk mitigation measures

- Wash hands after use of the concentrate product.
- Avoid contact with eyes
- Avoid splashes and spills during mixing and load ing (dilution).
- For outdoor uses, do not apply the product in case rain is expected within 24 hours.
- For outdoor uses by spray, avoid transfer to other areas by wind (drift).

For professional use only:

- Wear protective chemical resistant gloves classified under EN 374 or equivalent, chemical goggles consistent with EN 16321 or equivalent and a coverall consistent with EN 14605 or equivalent when handling the concentrate product (during dilution). The full titles of the EN standards are available in Section 6. – PPE material to be specified by the authorisation holder within the product information.

For non-professional use only:

- A child-proof closure is required.
- Keep out of reach of children and non-target animals or pets.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- If medical advice is needed, have product container or label at hand
- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.

Call 112 or an ambulance for medical assistance.

Information to healthcare personnel or doctor:

^(?) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

5.4. Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

- Keep out of reach of children and non-target animals or pets.
- Shelf-life: 2 years.
- Protect from frost.

6. OTHER INFORMATION

- P280 is not applicable for the non-professional user.

The full titles of the EN standards referenced in section 5.2 "Risk mitigation measures" are:

EN 374 - Protective gloves against dangerous chemicals and micro-organisms

EN 16321 - Eye and face protection for occupational use

EN 14605 - Protective clothing against liquid chemicals - Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM1_2		Market area: EU		
Authorisation number	EU-0028967-0005 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		27,0
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		8,23

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM1_3		Market area: EU		
Authorisation number	EU-0028967-0006 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		27,0
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		8,23

7.3. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM1_4	Market area: EU
	MAISON VERTE - Recharge pour spray désinfectant multi-usages	Market area: EU
	MAISON VERTE PRO - Recharge pour spray désinfectant multi-usages	Market area: EU
	MAISON VERTE PRO - Recharge pour spray désinfectant salle de bain	Market area: EU
	SANIVERT - Recharge pour spray désinfectant multi-usages	Market area: EU
	YOU - Recharge désinfectant toutes surfaces	Market area: EU
	YOU - Recharge désinfectant WC	Market area: EU
	SANILAK - Recharge Nettoyant désinfectant multi-usages Eucalyptus	Market area: EU
	SANILAK - Recharge Nettoyant désinfectant sanitaires Eucalyptus	Market area: EU
	SANILAK - Recharge Nettoyant désinfectant cuisine Eucalyptus	Market area: EU
	YOU - Refill All purpose disinfecting cleaner	Market area: EU

Authorisation number	EU-0028967-0007 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		27,0
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		8,23

7.4. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	SALVE FAM1_6		Market area: EU		
Authorisation number	EU-0028967-0008 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	20,89
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		18,0
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		5,49

7.5. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	SALVE FAM1_7		Market area: EU		
Authorisation number	EU-0028967-0009 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	20,89
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		18,0
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		5,49

7.6. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM1_8		Market area: EU		
Authorisation number	EU-0028967-0010 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	20,89
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		18,0
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		5,49

7.7. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM1_10		Market area: EU		
	SANILAK - Nettoyant désinfectant concentré Menthe		Market area: EU		
	SANILAK - Recharge Nettoyant désinfectant sols et surfaces Menthe		Market area: EU		
Authorisation number	EU-0028967-0011 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	15,66
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		13,5
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		4,11

7.8. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM1_11		Market area: EU		
Authorisation number	EU-0028967-0012 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	15,66
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		13,5
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		4,11

7.9. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM1_12		Market area: EU		
	MAISON VERTE - Recharge pour sol désinfectant multi-surfaces		Market area: EU		
	MAISON VERTE PRO - Recharge pour désinfectant sol		Market area: EU		
	MAISON VERTE PRO - Recharge pour désinfectant Multi-surfaces		Market area: EU		
	SANIVERT - Recharge désinfectant multi-surfaces		Market area: EU		
	YOU - Recharge désinfectant sols & surfaces		Market area: EU		
	SANILAK - Nettoyant désinfectant concentré Eucalyptus		Market area: EU		
	SANILAK - Recharge Nettoyant désinfectant sols et surfaces Eucalyptus		Market area: EU		
Authorisation number	EU-0028967-0013 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	15,66
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		13,5

D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		4,11
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7.10. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM1_14		Market area: EU		
Authorisation number	EU-0028967-0014 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		27,0
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		8,23

7.11. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM1_15		Market area: EU		
	TECH'LAB - Concentré détergent désinfectant sols & surfaces		Market area: EU		
Authorisation number	EU-0028967-0015 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	15,66
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		13,5
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		4,11

7.12. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM1_16		Market area: EU		
Authorisation number	EU-0028967-0016 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	15,66
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		13,5
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		4,11

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	meta-SPC3
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1.2. Suffix to the authorisation number

Number	1-3
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1.3. Product type(s)

Product type(s)	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
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2. META SPC 3 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	7,83	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		6,75	27,0

D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		1,32	3,52
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2.2. Type(s) of formulation of the meta SPC 3

Formulation(s)	SL – Soluble Concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	Causes skin irritation. Causes serious eye damage.
Precautionary statements	Wash hands thoroughly after handling. Wear protective gloves, protective clothing and eye protection. IF ON SKIN: Wash with plenty of water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor. Specific treatment (see supplemental first aid instruction on this label). If skin irritation occurs: Get medical advice. Take off contaminated clothing. And wash it before reuse.

4. AUTHORISED USE(S) OF THE META SPC 3

4.1. Use description

Table 5

Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in institutional, and industrial areas)

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage: Scientific name: Viruses Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor Outdoor — in institutional and industrial area

Application method(s)	Method: Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): 0,299% Number and timing of application: Mandatory target organisms: — Bacteria and yeasts: 0,299% w/w L-(+)-lactic acid, 5 minutes, 20°C Other target organisms: — Enveloped viruses: 0,299% w/w L-(+)-lactic acid, 5 minutes, 20°C Minimum in use concentration of surfactants shall be 0,29% for any future product included in this meta SPC.
Category(ies) of users	Professional
Pack sizes and packaging material	Refill caps: 20 – 100ml HDPE Bottles: 0,5 - 5 liters HDPE or PET Jerry can: 1-80 liters HDPE Drum: 10-210 liters HDPE IBC: 1 000 liters HDPE

4.1.1. *Use-specific instructions for use*

See general instructions for use

4.1.2. *Use-specific risk mitigation measures*

See general instructions for use

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use

4.2. Use description

Table 6

Use # 2 – Food and feed area disinfectants (disinfectant for all washable hard surfaces in institutional and industrial areas)

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage:
Field(s) of use	Indoor Outdoor — in institutional and industrial area (general)
Application method(s)	Method: Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): 0,299% Number and timing of application: Mandatory target organisms: — Bacteria and yeast: 0,299% w/w L-(+)-lactic acid, 5 minutes, 20°C Minimum in use concentration of surfactants shall be 0,29% for any future product included in this meta SPC.
Category(ies) of users	Professional
Pack sizes and packaging material	Refill caps: 20 – 100ml HDPE Bottles: 0,5 - 5 liters HDPE or PET Jerry can: 1-80 liters HDPE Drum: 10-210 liters HDPE IBC: 1 000 liters HDPE

4.2.1. Use-specific instructions for use

See general instructions for use

4.2.2. Use-specific risk mitigation measures

See general instructions for use

4.2.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general instructions for use

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use

5. **GENERAL DIRECTIONS FOR USE ^(*) OF THE META SPC 3**

5.1. **Instructions for use**

- Apply the product by fully wetting all surface for 5 minutes (apply approx. 18 sprays /m² or 20 ml/m² or fully cover the object to be disinfected).
- Apply only on non-porous surfaces.
- Inform the authorisation holder if the treatment is ineffective.
- Each product label shall give information on how the dilution should be made in order to guarantee the efficacy of the product. Since the concentration of L-(+)-lactic acid in products within this meta SPC can range from 7,83% to 31,33%, it is not possible to indicate all product dilution here.

Example for a product containing 7,83% L-(+)-lactic acid	Dilution of the product	Contact time
Bacterial and yeasticidal activity	0,299% (40 ml product, add water up to 1 liter)	5 minutes

The authorisation holder shall indicate on the label the relevant volume of product to be diluted in water on the label of each specific product.

5.2. **Risk mitigation measures**

- Wear protective chemical resistant gloves classified under EN 374 or equivalent, chemical goggles consistent with EN 16321 or equivalent and a coverall consistent with EN 14605 or equivalent when handling the concentrate product (during dilution). The full titless of the EN standard are available under section 6.
- PPE material to be specified by the authorisation holder within the product information.
- Wash hands after use of the concentrate product.
- Avoid contact with eyes.
- Avoid splashes and spills during mixing and loading (dilution).
- For outdoor uses, do not apply the product in case rain is expected within 24 hours.
- For outdoor uses by spray, avoid transfer to other areas by wind (drift).

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.

Call 112 or an ambulance for medical assistance.

Information to healthcare personnel or a doctor:

^(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.

The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

5.4. Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

- Shelf-life: 2 years.
- Protect from frost.

6. OTHER INFORMATION

The full titles of the EN standards referenced in section 5.2 "Risk mitigation measures" are:

EN 374 - Protective gloves against dangerous chemicals and micro-organisms

EN 16321 - Eye and face protection for occupational use

EN 14605 - Protective clothing against liquid chemicals - Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM2_1		Market area: EU		
Authorisation number	EU-0028967-0017 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	15,66
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		13,5
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		1,76

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM2_2		Market area: EU		
Authorisation number	EU-0028967-0018 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		27,0
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		3,52

7.3. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM2_6		Market area: EU		
Authorisation number	EU-0028967-0019 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	7,83
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		6,75
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		1,32

META SPC 4**1. META SPC 4 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 4 identifier**

Identifier	meta-SPC4
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1.2. Suffix to the authorisation number

Number	1-4
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1.3. **Product type(s)**

Product type(s)	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
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2. **META SPC 4 COMPOSITION**2.1. **Qualitative and quantitative information on the composition of the meta SPC 4**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	7,83	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		6,75	27,0
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		1,32	5,28

2.2. **Type(s) of formulation of the meta SPC 4**

Formulation(s)	SL – Soluble Concentrate
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3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4**

Hazard statements	Causes skin irritation. Causes serious eye damage. Contains Eucalyptol, Carvone and Limonene (Cool Mint fragrance). May produce an allergic reaction. Contains Methyl salicylate and Eugenol (Pure fragrance). May produce an allergic reaction.
Precautionary statements	Wash hands thoroughly after handling. Wear protective gloves, protective clothing and eye protection. IF ON SKIN: Wash with plenty of water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor. Specific treatment (see supplemental first aid instruction on this label). If skin irritation occurs: Get medical advice. Take off contaminated clothing. And wash it before reuse.

4. AUTHORISED USE(S) OF THE META SPC 4

4.1. Use description

Table 7

Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in institutional and industrial areas)

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage: Scientific name: Viruses Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor Outdoor — In institutional and industrial area
Application method(s)	Method: Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): 0,299% Number and timing of application: Mandatory target organisms: — Bacteria and yeasts: 0,299% w/w L-(+)-lactic acid, 5 minutes, 20°C Other target organisms: — Enveloped viruses: 0,299% w/w L-(+)-lactic acid, 5 minutes, 20°C Minimum in use concentration of surfactants shall be 0,29% for any future product included in this meta SPC.
Category(ies) of users	Professional
Pack sizes and packaging material	Refill caps: 20 – 100ml HDPE Bottles: 0,5 - 5 liters HDPE or PET Jerry can: 1-80 liters HDPE Drum: 10-210 liters HDPE IBC: 1 000 liters HDPE

4.1.1. *Use-specific instructions for use*

See general instructions for use

4.1.2. *Use-specific risk mitigation measures*

See general instructions for use

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use

4.2. **Use description**

Table 8

Use # 2 – Food and feed area disinfectants (disinfectant for all washable hard surfaces in institutional and industrial areas)

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage:
Field(s) of use	Indoor Outdoor — In institutional and industrial area
Application method(s)	Method: Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): 0,299% Number and timing of application: Mandatory target organisms: — Bacteria and yeast: 0,299% w/w L-(+)-lactic cid, 5 minutes, 20°C Minimum in use concentration of surfactants shall be 0,29% for any future product included in this meta SPC.

Category(ies) of users	Professional
Pack sizes and packaging material	Refill caps: 20 – 100ml HDPE Bottles: 0,5 - 5 liters HDPE or PET Jerry can: 1-80 liters HDPE Drum: 10-210 liters HDPE IBC: 1 000 liters HDPE

4.2.1. *Use-specific instructions for use*

See general instructions for use

4.2.2. *Use-specific risk mitigation measures*

See general instructions for use

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use

5. **GENERAL DIRECTIONS FOR USE ⁽⁴⁾ OF THE META SPC 4**

5.1. **Instructions for use**

- Apply the product by fully wetting all surface for 5 minutes (apply approx. 18 sprays /m² or 20 ml/m² or fully cover the object to be disinfected).
- Apply only on non porous surfaces.
- Inform the authorisation holder if the treatment is ineffective.
- Each product label shall give information on how the dilution should be made in order to guarantee the efficacy of the product. Since the concentration of L-(+)-lactic acid in products within this meta SPC can range from 7,83% to 31,33%, it is not possible to indicate all product dilution here.

Example for a product containing 7,83% L-(+)-lactic acid	Dilution of the product	Contact time
Bacterial and yeasticidal activity	0,299% (40 ml product, add water up to 1 liter)	5 minutes

The authorisation holder shall indicate on the label the relevant volume of product to be diluted in water on the label of each specific product.

⁽⁴⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 4.

5.2. Risk mitigation measures

- Wear protective chemical resistant gloves classified under EN 374 or equivalent, chemical goggles consistent with EN 16321 or equivalent and a coverall consistent with EN 14605 or equivalent when handling the concentrate product (during dilution). The full titles of the EN standards are available under section 6.
- PPE material to be specified by the authorisation holder within the product information.
- Wash hands after use of the concentrate product.
- Avoid contact with eyes.
- Avoid splashes and spills during mixing and loading (dilution).
- For outdoor uses, do not apply the product in case rain is expected within 24 hours.
- For outdoor uses by spray, avoid transfer to other areas by wind (drift).

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.

Call 112 or an ambulance for medical assistance.

Information to healthcare personnel or a doctor:

The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.
- IF INHALED: If symptoms occur call a POISON CENTER or a doctor.

5.4. Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

- Shelf-life: 2 years.
- Protect from frost.

6. OTHER INFORMATION

The full titles of the EN standards referenced in section 5.2 "Risk mitigation measures" are:

EN 374 - Protective gloves against dangerous chemicals and micro-organisms

EN 16321 - Eye and face protection for occupational use

EN 14605 - Protective clothing against liquid chemicals - Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM2_3		Market area: EU		
	ATOUT-VERT - DD303		Market area: EU		
	SANILAK - Recharge Nettoyant Désinfectant Multi-usages Menthe		Market area: EU		
	SANILAK - Recharge Nettoyant Désinfectant Sanitaires Menthe		Market area: EU		
	SANILAK - Recharge Nettoyant Désinfectant Cuisine Menthe		Market area: EU		
Authorisation number	EU-0028967-0020 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		27,0
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		5,28

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM2_4		Market area: EU		
Authorisation number	EU-0028967-0021 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		27,0
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		5,28

7.3. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM2_5		Market area: EU		
	ATOUT-VERT - DDP38		Market area: EU		
Authorisation number	EU-0028967-0022 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	7,83
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		6,75
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		1,32

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 5 identifier

Identifier	meta-SPC5
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1.2. Suffix to the authorisation number

Number	1-5
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1.3. Product type(s)

Product type(s)	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT03 - Veterinary hygiene (Disinfectants) PT04 - Food and feed area (Disinfectants)
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2. META SPC 5 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	31,33	31,33

Sodium octyl ether carboxylate		Non-active substance	53563-70-5		28,8	28,8
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		3,52	3,52

2.2. Type(s) of formulation of the meta SPC 5

Formulation(s)	SL – Soluble Concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	Causes skin irritation. Causes serious eye damage.
Precautionary statements	Wash hands thoroughly after handling. Wear protective gloves, protective clothing and eye protection. IF ON SKIN:Wash with plenty of water. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor. Specific treatment (see supplemental first aid instruction on this label). If skin irritation occurs:Get medical advice. Take off contaminated clothing.And wash it before reuse.

4. AUTHORISED USE(S) OF THE META SPC 5

4.1. Use description

Table 9

Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in institutional, medical, and industrial areas)

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage: Scientific name: Viruses Common name: Enveloped viruses Development stage:

Field(s) of use	Indoor Outdoor — In institutional, medical and industrial area
Application method(s)	Method: Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion except in medical areas, mopping Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): 0,4485% Number and timing of application: Mandatory target organisms: — Bacteria and yeasts: 0,4485% w/w L-(+)-lactic acid, 5 minutes, 20°C Other target organisms: — Enveloped viruses: 0,4485% w/w L-(+)-lactic acid, 5 minutes, 20°C The concentrated product is to be diluted at 1,5% v/v before use.
Category(ies) of users	Professional
Pack sizes and packaging material	Bottles: 0,5 - 5 liters HDPE or PET Jerry can: 1-80 liters HDPE Drum: 10-210 liters HDPE IBC: 1 000 liters HDPE

4.1.1. *Use-specific instructions for use*

See general instructions for use

4.1.2. *Use-specific risk mitigation measures*

See general instructions for use

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use

4.2. Use description

Table 10

Use # 2 – Food and feed area disinfectants (disinfectant for all washable hard surfaces in institutional and industrial (food industry) areas)

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage:
Field(s) of use	Indoor Outdoor — In institutional and industrial (food industry (general, meat (except slaughterhouses) and milk industries)) area
Application method(s)	Method: Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): 0,4485% to 0,598% Number and timing of application: General disinfection and meat industries Mandatory target organisms: — Bacteria and yeast: 0,4485% to 0,598% w/w L-(+)-lactic acid, 5 minutes, 20°C The concentrated product is to be diluted between 1,5% and 2% v/v before use. Milk industries Mandatory target organisms: — Bacteria and yeast: 0,598% w/w L-(+)-lactic acid, 5 minutes, 20°C The concentrated product is to be diluted at 2% v/v before use.
Category(ies) of users	Professional
Pack sizes and packaging material	Bottles: 0,5 - 5 liters HDPE or PET Jerry can: 1-80 liters HDPE Drum: 10-210 liters HDPE IBC: 1 000 liters HDPE

4.2.1. *Use-specific instructions for use*

See general instructions for use

4.2.2. *Use-specific risk mitigation measures*

See general instructions for use

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use

4.3. **Use description**

Table 11

**Use # 3 – Disinfectants used to disinfect the materials and surfaces associated with the housing of animals
(disinfectants for all washable hard surfaces in veterinary area)**

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: other: bacteria Common name: Bacteria Development stage: Scientific name: other: yeast Common name: Yeast Development stage:
Field(s) of use	Indoor Outdoor
Application method(s)	Method: Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): 0,299% Number and timing of application: Mandatory target organisms: — Bacteria and yeast: 0,299% w/w L-(+)-lactic acid 30 minutes, 10°C The concentrated product is to be diluted at 1% v/v before use.
Category(ies) of users	Professional

Pack sizes and packaging material	Bottles: 0,5 - 5 liters HDPE or PET Jerry can: 1-80 liters HDPE Drum: 10-210 liters HDPE IBC: 1 000 liters HDPE
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4.3.1. *Use-specific instructions for use*

— Clean carefully the surfaces before application of the product.

4.3.2. *Use-specific risk mitigation measures*

See general instructions for use

4.3.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use

4.3.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use

4.3.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use

5. **GENERAL DIRECTIONS FOR USE ^(*) OF THE META SPC 5**

5.1. **Instructions for use**

- Apply the product by fully wetting all surface for 5 to 30 minutes (apply approx. 18 sprays /m² or 20 ml/m² or fully cover the object to be disinfected).
- Apply only on non-porous surfaces.
- Inform the authorisation holder if the treatment is ineffective.

5.2. **Risk mitigation measures**

- Wear protective chemical resistant gloves classified under EN 374 or equivalent, chemical goggles consistent with EN 16321 or equivalent and a coverall consistent with EN 14605 or equivalent when handling the concentrate product (during dilution). The full text of the EN standard are available under section 6.
- PPE material to be specified by the authorisation holder within the product information.
- Wash hands after use of the concentrate product.
- Avoid contact with eyes.
- Avoid splashes and spills during mixing and loading (dilution).
- For outdoor uses, do not apply the product in case rain is expected within 24 hours.
- For outdoor uses by spray, avoid transfer to other areas by wind (drift).

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

^(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 5.

— IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.

Call 112 or an ambulance for medical assistance.

Information to healthcare personnel or a doctor:

The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

— IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.

— IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

5.4. Instructions for safe disposal of the product and its packaging

— Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.

— Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

— Shelf-life: 2 years.

— Protect from frost.

6. OTHER INFORMATION

— The product is a foaming formulation.

The full titles of the EN standards referenced in section 5.2 "Risk mitigation measures" are:

EN 374 - Protective gloves against dangerous chemicals and micro-organisms

EN 16321 - Eye and face protection for occupational use

EN 14605 - Protective clothing against liquid chemicals - Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM3_1		Market area: EU		
	CLEAN DESINFECTANT		Market area: EU		
	GERM D		Market area: EU		
Authorisation number	EU-0028967-0023 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		28,8
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		3,52

META SPC 6**1. META SPC 6 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 6 identifier**

Identifier	meta-SPC6
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1.2. Suffix to the authorisation number

Number	1-6
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1.3. Product type(s)

Product type(s)	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
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2. META SPC 6 COMPOSITION**2.1. Qualitative and quantitative information on the composition of the meta SPC 6**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	31,33	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		28,8	28,8
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		5,28	5,28

2.2. Type(s) of formulation of the meta SPC 6

Formulation(s)	SL – Soluble Concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

Hazard statements	Causes skin irritation. Causes serious eye damage. Contains Eucalyptol and Carvone. May produce an allergic reaction.
Precautionary statements	Wash hands thoroughly after handling. Wear protective gloves, protective clothing and eye protection. IF ON SKIN: Wash with plenty of water.

	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor. Specific treatment (see supplemental first aid instruction on this label). If skin irritation occurs: Get medical advice. Take off contaminated clothing. And wash it before reuse.
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4. AUTHORISED USE(S) OF THE META SPC 6

4.1. Use description

Table 12

Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in medical area)

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage: Scientific name: Viruses Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor Outdoor — in medical area
Application method(s)	Method: Spraying, spreading, wiping, foam application, brush treatment, dip treatment, mopping Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): 0,4485% Number and timing of application: Mandatory target organisms: — Bacteria and yeast: 0,4485% w/w L-(+)-lactic acid, 5 minutes, 20°C Other target organisms: — Enveloped viruses: 0,4485% w/w L-(+)-lactic acid, 5 minutes, 20°C The concentrated product is to be diluted at 1,5 % before use.
Category(ies) of users	Professional

Pack sizes and packaging material	Bottles: 0,5 - 5 liters HDPE or PET Jerry can: 1-80 liters HDPE Drum: 10-210 liters HDPE IBC: 1 000 liters HDPE
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4.1.1. *Use-specific instructions for use*

See general instructions for use

4.1.2. *Use-specific risk mitigation measures*

See general instructions for use

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use

5. **GENERAL DIRECTIONS FOR USE ⁽⁹⁾ OF THE META SPC 6**

5.1. **Instructions for use**

- Apply the product by fully wetting all surface for 5 minutes (apply approx. 18 sprays /m² or 20 ml/m² or fully cover the object to be disinfected).
- Apply only on non porous surfaces.
- Inform the authorisation holder if the treatment is ineffective.

5.2. **Risk mitigation measures**

- Wear protective chemical resistant gloves classified under EN 374 or equivalent, chemical goggles consistent with EN 16321 or equivalent and a coverall consistent with EN 14605 or equivalent when handling the concentrate product (during dilution). The full titless of the EN standard are available under section 6.
- PPE material to be specified by the authorisation holder within the product information.
- Wash hands after use of the concentrate product.
- Avoid contact with eyes.
- Avoid splashes and spills during mixing and loading (dilution).
- For outdoor uses, do not apply the product in case rain is expected within 24 hours.
- For outdoor uses by spray, avoid transfer to other areas by wind (drift).

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.

⁽⁹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 6.

- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.

Call 112 or an ambulance for medical assistance.

Information to healthcare personnel or a doctor:

- The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid
- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor

5.4. Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

- Shelf-life: 2 years.
- Protect from frost.

6. OTHER INFORMATION

The full titles of the EN standards referenced in section 5.2 "Risk mitigation measures" are:

EN 374 - Protective gloves against dangerous chemicals and micro-organisms

EN 16321 - Eye and face protection for occupational use

EN 14605 - Protective clothing against liquid chemicals - Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM3_2		Market area: EU		
Authorisation number	EU-0028967-0024 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		28,8
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		5,28

META SPC 7**1. META SPC 7 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 7 identifier**

Identifier	meta-SPC7
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1.2. Suffix to the authorisation number

Number	1-7
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1.3. Product type(s)

Product type(s)	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT03 - Veterinary hygiene (Disinfectants) PT04 - Food and feed area (Disinfectants)
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2. META SPC 7 COMPOSITION**2.1. Qualitative and quantitative information on the composition of the meta SPC 7**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	31,33	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		24,93	24,93
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		3,52	3,52

2.2. Type(s) of formulation of the meta SPC 7

Formulation(s)	SL – Soluble Concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7

Hazard statements	Causes skin irritation. Causes serious eye damage.
Precautionary statements	Wash hands thoroughly after handling. Wear protective gloves, protective clothing and eye protection.

	IF ON SKIN: Wash with plenty of water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor. Specific treatment (see supplemental first aid instruction on this label). If skin irritation occurs: Get medical advice. Take off contaminated clothing. And wash it before reuse.
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4. AUTHORISED USE(S) OF THE META SPC 7

4.1. Use description

Table 13

Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in domestic, institutional and industrial areas)

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage: Scientific name: Viruses Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor Outdoor — In domestic, institutional and industrial area
Application method(s)	Method: Wiping, moping or brush, spraying, soaking or dipping (immersion) Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): 0,299% Number and timing of application: Mandatory target organisms: — Bacteria and yeasts: 0,299% w/w L-(+)-lactic acid, 5 minutes, 20°C Other target organisms: — Enveloped viruses: 0,299% w/w L-(+)-lactic acid, 5 minutes, 20°C The concentrated product is to be diluted at 1% v/v before use.

Category(ies) of users	Professional
Pack sizes and packaging material	Bottles: 0,5 - 5 liters HDPE or PET Jerry can: 1-80 liters HDPE Drum: 10-210 liters HDPE IBC: 1 000 liters HDPE Soft container: 1,5, 2,5 liters Low density polyethylene (LDPE)

4.1.1. *Use-specific instructions for use*

Apply the product by fully wetting all surface for 5 minutes (apply approx. 18 sprays/m² or 20 ml/m² or fully cover the object to be disinfected).

4.1.2. *Use-specific risk mitigation measures*

See general instructions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use.

4.2. **Use description**

Table 14

Use # 2 – Food and feed area disinfectants (disinfectant for all washable hard surfaces in domestic, institutional and industrial (food industry) areas)

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage: Scientific name: Virus Common name: Enveloped viruses only Development stage:
Field(s) of use	Indoor Outdoor — In domestic, institutional and food industry areas

Application method(s)	Method: Wiping, moping or brush, spraying, soaking or dipping (immersion) Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): 0,299% Number and timing of application: Mandatory target organisms: — Bacteria and yeast: 0,299% w/w L-(+)-lactic acid, 5 minutes, 20°C Other target organisms: — Enveloped viruses: 0,299% w/w L-(+)-lactic acid, 5 minutes, 20°C The concentrated product is to be diluted at 1% v/v before use as indicated on label.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottles: 0,5 - 5 liters HDPE or PET Jerry can: 1-80 liters HDPE Drum: 10-210 liters HDPE IBC: 1 000 liters HDPE Soft container: 1,5, 2,5 liters LDPE

4.2.1. Use-specific instructions for use

- Apply the product by fully wetting all surface for 5 minutes (apply approx. 18 sprays/m² or 20 ml/m² or fully cover the object to be disinfected).

4.2.2. Use-specific risk mitigation measures

See general instructions for use

4.2.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general instructions for use

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general instructions for use

4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general instructions for use

4.3. Use description

Table 15

**Use # 3 – Disinfectants used to disinfect the materials and surfaces associated with the housing of animals
(disinfectants for all washable hard surfaces in veterinary area)**

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeast Common name: Yeasts Development stage:
Field(s) of use	Indoor Outdoor -
Application method(s)	Method: Wiping, moping or brush, spraying, soaking or dipping (immersion) Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): 0,748% Number and timing of application: Mandatory target organisms: — Bacteria and yeast: 0,748% w/w L-(+)-lactic acid, 30 minutes, 10°C The concentrated product is to be diluted at 2,5% v/v before use as indicated on label.
Category(ies) of users	Professional
Pack sizes and packaging material	Bottles: 0,5 - 5 liters HDPE or PET Jerry can: 1-80 liters HDPE Drum: 10-210 liters HDPE IBC: 1 000 liters HDPE Soft container: 1,5, 2,5 liters LDPE

4.3.1. Use-specific instructions for use

- Clean carefully the surfaces before application of the product.
- Apply the product by fully wetting all surface for 30 minutes (apply approx. 18 sprays/m² or 20 ml/m² or fully cover the object to be disinfected).

4.3.2. *Use-specific risk mitigation measures*

See general instructions for use

4.3.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use

4.3.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use

4.3.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use

5. **GENERAL DIRECTIONS FOR USE ⁽⁷⁾ OF THE META SPC 7**

5.1. **Instructions for use**

- Apply only on non porous surfaces.
- Inform the authorisation holder if the treatment is ineffective.

5.2. **Risk mitigation measures**

- Wear protective chemical resistant gloves classified under EN 374 or equivalent, chemical goggles consistent with EN 16321 or equivalent and a coverall consistent with EN 14605 or equivalent when handling the concentrate product (during dilution). The full titless of the EN standard are available under section 6.
- PPE material to be specified by the authorisation holder within the product information.
- Wash hands after use of the concentrate product.
- Avoid contact with eyes.
- Avoid splashes and spills during mixing and loading (dilution).
- For outdoor uses, do not apply the product in case rain is expected within 24 hours.
- For outdoor uses by spray, avoid transfer to other areas by wind (drift).

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.

Call 112 or an ambulance for medical assistance.

Information to healthcare personnel or a doctor:

The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

⁽⁷⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 7.

5.4. Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

- Shelf-life: 2 years.
- Protect from frost.

6. OTHER INFORMATION

The full titles of the EN standards referenced in section 5.2 "Risk mitigation measures" are:

EN 374 - Protective gloves against dangerous chemicals and micro-organisms

EN 16321 - Eye and face protection for occupational use

EN 14605 - Protective clothing against liquid chemicals - Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 7**7.1. Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	SALVE 15		Market area: EU		
Authorisation number	EU-0028967-0025 1-7				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	31,33
Sodium octyl ether carboxylate		Non-active substance	53563-70-5		24,93
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Non-active substance	110615-47-9		3,52

META SPC 8**1. META SPC 8 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 8 identifier**

Identifier	meta-SPC8
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1.2. Suffix to the authorisation number

Number	1-8
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1.3. **Product type(s)**

Product type(s)	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
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2. **META SPC 8 COMPOSITION**2.1. **Qualitative and quantitative information on the composition of the meta SPC 8**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	0,627	1,566

2.2. **Type(s) of formulation of the meta SPC 8**

Formulation(s)	AL – Any other liquids
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3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 8**

Hazard statements	
Precautionary statements	

4. **AUTHORISED USE(S) OF THE META SPC 8**4.1. **Use description**

Table 16

Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in domestic, institutional and industrial areas)

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage: Scientific name: Viruses Common name: Enveloped viruses Development stage:

Field(s) of use	Indoor Outdoor — In domestic, institutional and industrial areas.
Application method(s)	Method: Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): 0 Number and timing of application: Ready to use products. Contact time: 5 minutes, 20°C
Category(ies) of users	Professional General public (non-professional)
Pack sizes and packaging material	Package size for non-professional is restricted to maximum 3 liters and packaging above 1 liter should be equipped with a handle. Sprays (SP05): 0,5 liter - 0,75 liter HDPE or PET Bottles: 0,5 - 5 liters HDPE or PET Jerry can: 1-80 liters HDPE (only for professional users) Drum: 10-210 liters HDPE (only for professional users) IBC: 1 000 liters HDPE (only for professional users)

4.1.1. *Use-specific instructions for use*

See general instructions for use

4.1.2. *Use-specific risk mitigation measures*

See general instructions for use

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use

4.2. Use description

Table 17

Use # 2 – Food and feed area disinfectants (disinfectant for all washable hard surfaces in domestic, institutional and industrial areas)

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage:
Field(s) of use	Indoor Outdoor — In domestic, institutional and industrial (food industry (general)) areas.
Application method(s)	Method: Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion> Detailed description: -
Application rate(s) and frequency	Application Rate: -> Dilution (%): 0> Number and timing of application:> Ready to use products.> Contact time: 5 minutes, 20°C
Category(ies) of users	Professional General public (non-professional)
Pack sizes and packaging material	Package size for non-professional is restricted to maximum 3 liters and packaging above 1 liter should be equipped with a handle.> Sprays (SP05): 0,5 liter - 0,75 liter HDPE or PET> Bottles: 0,5 - 5 liters HDPE or PET> Jerry can: 1-80 liters HDPE (only for professional users) Drum: 10-210 liters HDPE (only for professional users) IBC: 1 000 liters HDPE (only for professional users)

4.2.1. Use-specific instructions for use

See general instructions for use

4.2.2. Use-specific risk mitigation measures

See general instructions for use

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use

5. **GENERAL DIRECTIONS FOR USE ⁽⁸⁾ OF THE META SPC 8**

5.1. **Instructions for use**

- Apply the product by fully wetting all surface for 5 minutes (apply approx. 18 sprays /m² or 20 ml/m² or fully cover the object to be disinfected).
- Apply only on non porous surfaces.
- Inform the authorisation holder if the treatment is ineffective.
- Comply with the instructions for use.

5.2. **Risk mitigation measures**

- For outdoor uses, do not apply the product in case rain is expected within 24 hours.
- For outdoor uses by spray, avoid transfer to other areas by wind (drift).

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

- If medical advice is needed, have product container or label at hand
- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
- IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

5.4. **Instructions for safe disposal of the product and its packaging**

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

- Keep out of reach of children and non-target animals or pets.
- Shelf-life: 2 years.
- Protect from frost.

⁽⁸⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 8.

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 8

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM5_1		Market area: EU		
Authorisation number	EU-0028967-0026 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	0,627

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM5_2		Market area: EU		
Authorisation number	EU-0028967-0027 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	0,627

7.3. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SANILAK - Nettoyant désinfectant multi-usages Eucalyptus		Market area: EU		
	SANILAK - Nettoyant désinfectant sanitaires Eucalyptus		Market area: EU		
	SANILAK - Nettoyant désinfectant cuisine Eucalyptus		Market area: EU		
	SALVE FAM5_3		Market area: EU		
Authorisation number	EU-0028967-0028 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	0,627

7.4. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM5_4		Market area: EU		
	YOU - All purpose disinfecting cleaner		Market area: EU		
	MAISON VERTE - Désinfectant		Market area: EU		
	MAISON VERTE PRO - Désinfectant Multi-usages		Market area: EU		
	MAISON VERTE PRO - Désinfectant Salle de Bain		Market area: EU		
	SANIVERT - Désinfectant		Market area: EU		
	YOU - Nettoyant désinfectant toutes surfaces		Market area: EU		
	YOU - Désinfectant WC détartrant		Market area: EU		
Authorisation number	EU-0028967-0029 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	0,627

7.5. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM5_5		Market area: EU		
Authorisation number	EU-0028967-0030 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,566

7.6. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM5_6		Market area: EU		
	SANILAK - Nettoyant désinfectant sols et surfaces		Market area: EU		
Authorisation number	EU-0028967-0031 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,566

7.7. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM5_7		Market area: EU		
	SANILAK - Nettoyant désinfectant sols et surfaces Eucalyptus		Market area: EU		
Authorisation number	EU-0028967-0032 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,566

7.8. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM5_8		Market area: EU		
	MAISON VERTE - Désinfectant Multi-surfaces		Market area: EU		
	MAISON VERTE PRO - Désinfectant Sol		Market area: EU		
	MAISON VERTE PRO - Désinfectant Multi-surfaces		Market area: EU		
	SANIVERT - Désinfectant Multi-surfaces		Market area: EU		
	YOU - Désinfectant sols & surfaces		Market area: EU		
Authorisation number	EU-0028967-0033 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,566

META SPC 9

1. META SPC 9 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 9 identifier

Identifier	meta-SPC9
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1.2. Suffix to the authorisation number

Number	1-9
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1.3. **Product type(s)**

Product type(s)	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
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2. **META SPC 9 COMPOSITION**2.1. **Qualitative and quantitative information on the composition of the meta SPC 9**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	0,627	0,627

2.2. **Type(s) of formulation of the meta SPC 9**

Formulation(s)	AL – Any other liquids
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3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 9**

Hazard statements	
Precautionary statements	

4. **AUTHORISED USE(S) OF THE META SPC 9**4.1. **Use description**

Table 18

Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in domestic, institutional and industrial areas)

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage: Scientific name: Viruses Common name: Enveloped viruses Development stage:

Field(s) of use	Indoor Outdoor — In domestic, institutional and industrial area.
Application method(s)	Method: Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): - Number and timing of application: Ready to use products. Contact time: 5 minutes, 20°C
Category(ies) of users	Professional General public (non-professional)
Pack sizes and packaging material	Package size for non-professional is restricted to maximum 3 liters and packaging above 1 liter should be equipped with a handle Sprays (SP05): 0,5 liter - 0,75 liter HDPE or PET Bottles: 0,5 - 5 liters HDPE or PET Jerry can: 1-80 liters HDPE (only for professional users) Drum: 10-210 liters HDPE (only for professional users)

4.1.1. *Use-specific instructions for use*

See general instructions for use

4.1.2. *Use-specific risk mitigation measures*

See general instructions for use

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use

4.2. Use description

Table 19

Use # 2 – Food and feed area disinfectants (disinfectant for all washable hard surfaces in domestic, institutional and industrial areas)

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage:
Field(s) of use	Indoor Outdoor — In domestic, institutional and industrial (general) area
Application method(s)	Method: Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping Detailed description: — without mechanical action
Application rate(s) and frequency	Application Rate: - Dilution (%): - Number and timing of application: Ready to use products. Contact time: 5 minutes, 20°C
Category(ies) of users	Professional General public (non-professional)
Pack sizes and packaging material	Package size for non-professional is restricted to maximum 3 liters and packaging above 1 liter should be equipped with a handle. Sprays (SP05): 0,5 liter - 0,75 liter HDPE or PET Bottles: 0,5 - 5 liters HDPE or PET Jerry can: 1-80 liters HDPE (only for professional users) Drum: 10-210 liters HDPE (only for professional users)

4.2.1. Use-specific instructions for use

See general instructions for use

4.2.2. Use-specific risk mitigation measures

See general instructions for use

- 4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general instructions for use

- 4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general instructions for use

- 4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general instructions for use

5. **GENERAL DIRECTIONS FOR USE ⁽⁹⁾ OF THE META SPC 9**

5.1. **Instructions for use**

- Apply the product by fully wetting all surface for 5 minutes (apply approx. 18 sprays /m² or 20 ml/m² or fully cover the object to be disinfected).
- Comply with the instructions for use.
- Apply only on non-porous surfaces

5.2. **Risk mitigation measures**

- For outdoor uses, do not apply the product in case rain is expected within 24 hours.
- For outdoor uses by spray, avoid transfer to other areas by wind (drift).

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

- If medical advice is needed, have product container or label at hand
- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
- IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

5.4. **Instructions for safe disposal of the product and its packaging**

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

- Keep out of reach of children and non-target animals or pets.
- Shelf-life: 2 years.
- Protect from frost.

6. **OTHER INFORMATION**

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⁽⁹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 9.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 9

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM6_1		Market area: EU		
Authorisation number	EU-0028967-0034 1-9				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	0,627

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM6_2		Market area: EU		
	SANILAK - Nettoyant désinfectant multi-usages Menthe		Market area: EU		
	SANILAK - Nettoyant désinfectant sanitaires Menthe		Market area: EU		
	SANILAK - Nettoyant désinfectant cuisine Menthe		Market area: EU		
Authorisation number	EU-0028967-0035 1-9				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	0,627

7.3. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVE FAM6_3		Market area: EU		
Authorisation number	EU-0028967-0036 1-9				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	0,627

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2023/1759

of 11 September 2023

on the harmonised standards for household dishwashers drafted in support of Regulation (EU) 2019/2022 and Delegated Regulation (EU) 2019/2017

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ⁽¹⁾, and in particular Article 10(6) thereof,

Whereas:

- (1) In accordance with Article 9(2) of Directive 2009/125/EC of the European Parliament and of the Council ⁽²⁾, Member States are to regard a product for which harmonised standards have been applied, the reference numbers of which have been published in the *Official Journal of the European Union*, as conforming to all the relevant requirements of the applicable implementing measure to which such standards relate. Article 4 of Commission Regulation (EU) 2019/2022 ⁽³⁾ and Annex III thereto lay down the relevant measurement and calculation requirements for household dishwashers. Annex III to Regulation (EU) 2019/2022 was amended by Commission Regulation (EU) 2021/341 ⁽⁴⁾.
- (2) In accordance with Article 13 of Regulation (EU) 2017/1369 of the European Parliament and of the Council ⁽⁵⁾ after the adoption of a delegated act pursuant to Article 16 of that Regulation setting specific labelling requirements the Commission is to publish references to the harmonised standards that satisfy the relevant measurement and calculation requirements of the delegated act in the *Official Journal of the European Union*. Where such harmonised standards are applied during the conformity assessment of a product, the model is to be presumed to be in conformity with the relevant measurement and calculation requirements of the delegated act. Article 3 of Commission Delegated Regulation (EU) 2019/2017 ⁽⁶⁾ and Annex IV thereto lay down measurement and calculation requirements for household dishwashers. Annex IV to Delegated Regulation (EU) 2019/2017 was amended by Commission Delegated Regulation (EU) 2021/340 ⁽⁷⁾.

⁽¹⁾ OJ L 316, 14.11.2012, p. 12.

⁽²⁾ Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (OJ L 285, 31.10.2009, p. 10).

⁽³⁾ Commission Regulation (EU) 2019/2022 of 1 October 2019 laying down ecodesign requirements for household dishwashers pursuant to Directive 2009/125/EC of the European Parliament and of the Council amending Commission Regulation (EC) No 1275/2008 and repealing Commission Regulation (EU) No 1016/2010 (OJ L 315, 5.12.2019, p. 267).

⁽⁴⁾ Commission Regulation (EU) 2021/341 of 23 February 2021 amending Regulations (EU) 2019/424, (EU) 2019/1781, (EU) 2019/2019, (EU) 2019/2020, (EU) 2019/2021, (EU) 2019/2022, (EU) 2019/2023 and (EU) 2019/2024 with regard to ecodesign requirements for servers and data storage products, electric motors and variable speed drives, refrigerating appliances, light sources and separate control gears, electronic displays, household dishwashers, household washing machines and household washer-dryers and refrigerating appliances with a direct sales function (OJ L 68, 26.2.2021, p. 108).

⁽⁵⁾ Regulation (EU) 2017/1369 of the European Parliament and of the Council of 4 July 2017 setting a framework for energy labelling and repealing Directive 2010/30/EU (OJ L 198, 28.7.2017, p. 1).

⁽⁶⁾ Commission Delegated Regulation (EU) 2019/2017 of 11 March 2019 supplementing Regulation (EU) 2017/1369 of the European Parliament and of the Council with regard to energy labelling of household dishwashers and repealing Commission Delegated Regulation (EU) No 1059/2010 (OJ L 315, 5.12.2019, p. 134).

⁽⁷⁾ Commission Delegated Regulation (EU) 2021/340 of 17 December 2020 amending Delegated Regulations (EU) 2019/2013, (EU) 2019/2014, (EU) 2019/2015, (EU) 2019/2016, (EU) 2019/2017 and (EU) 2019/2018 with regard to energy labelling requirements for electronic displays, household washing machines and household washer-dryers, light sources, refrigerating appliances, household dishwashers, and refrigerating appliances with a direct sales function (OJ L 68, 26.2.2021, p. 62).

- (3) By Implementing Decision C(2020) 4329 ⁽⁸⁾, the Commission made a request to the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (Cenelec) and the European Telecommunications Standards Institute (ETSI) to revise existing harmonised standards on household dishwashers, household washing machines and household washer-dryers in support of Regulation (EU) 2019/2022 and Commission Regulation (EU) 2019/2023 ⁽⁹⁾, Delegated Regulation (EU) 2019/2017 and Commission Delegated Regulation (EU) 2019/2014 ⁽¹⁰⁾.
- (4) On the basis of the request set out in Implementing Decision C(2020) 4329, Cenelec revised the harmonised standard EN 60436:2020 as amended by EN 60436:2020/A11:2020 and corrected by EN 60436:2020/AC:2020-06 in order to take account of the technical and scientific progress, bring editorial changes, and align rounding of reported numbers in alignment with amendments made by Regulation (EU) 2021/341 and Delegated Regulation (EU) 2021/340. This resulted in the adoption of amendment EN 60436:2020/A12:2022 to that harmonised standard.
- (5) The Commission, together with Cenelec, has assessed whether amendment EN 60436:2020/A12:2022 to the harmonised standard EN 60436:2020 as amended by EN 60436:2020/A11:2020 and corrected by EN 60436:2020/AC:2020-06 complies with the request set out in Implementing Decision C(2020) 4329.
- (6) The harmonised standard EN 60436:2020, as amended by EN 60436:2020/A11:2020 and EN 60436:2020/A12:2022 and corrected by EN 60436:2020/AC:2020-06, satisfies the requirements which it aims to cover and which are set out in Regulation (EU) 2019/2022 and Delegated Regulation (EU) 2019/2017.
- (7) It is therefore appropriate to publish the reference of harmonised standard EN 60436:2020, as amended by EN 60436:2020/A11:2020 and EN 60436:2020/A12:2022 and corrected by EN 60436:2020/AC:2020-06 in the *Official Journal of the European Union*.
- (8) Harmonised standard EN 60436:2020, as amended by EN 60436:2020/A11:2020 and EN 60436:2020/A12:2022 and corrected by EN 60436:2020/AC:2020-06 replaces harmonised standard EN 60436:2020, as amended by EN 60436:2020/A11:2020 and corrected by EN 60436:2020/AC:2020-6. It is therefore necessary to withdraw the reference of that standard from the *Official Journal of the European Union*.
- (9) The references of harmonised standards drafted in support of Delegated Regulation (EU) 2019/2017 and Regulation (EU) 2019/2022 are currently published by Commission Implementing Decision (EU) 2021/913 ⁽¹¹⁾ with restrictions. In view of the amendment EN 60436:2020/A12:2022 those restrictions are no longer necessary.
- (10) Since a number of substantial amendments are to be made to Implementing Decision (EU) 2021/913, it should be replaced in the interest of clarity.

⁽⁸⁾ Commission Implementing Decision C(2020)4329 of 1 July 2020 on a standardisation request to the European Committee for Standardisation, the European Committee for Electrotechnical Standardisation and the European Telecommunications Standards Institute as regards ecodesign and energy labelling requirements for household dishwashers, household washing machines and household washer-dryers in support of Commission Regulations (EU) 2019/2022 and (EU) 2019/2023 and Commission Delegated Regulations (EU) 2019/2017 and (EU) 2019/2014.

⁽⁹⁾ Commission Regulation (EU) 2019/2023 of 1 October 2019 laying down ecodesign requirements for household washing machines and household washer-dryers pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending Commission Regulation (EC) No 1275/2008 and repealing Commission Regulation (EU) No 1015/2010 (OJ L 315, 5.12.2019, p. 285).

⁽¹⁰⁾ Commission Delegated Regulation (EU) 2019/2014 of 11 March 2019 supplementing Regulation (EU) 2017/1369 of the European Parliament and of the Council with regard to energy labelling of household washing machines and household washer-dryers and repealing Commission Delegated Regulation (EU) No 1061/2010 and Commission Directive 96/60/EC (OJ L 315, 5.12.2019, p. 29).

⁽¹¹⁾ Commission Implementing Decision (EU) 2021/913 of 3 June 2021 on the harmonised standards for household dishwashers drafted in support of Regulation (EU) 2019/2022 and Delegated Regulation (EU) 2019/2017 (OJ L 199, 7.6.2021, p. 13).

- (11) Compliance with a harmonised standard confers a presumption of conformity with the corresponding requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the date of its publication,

HAS ADOPTED THIS DECISION:

Article 1

The reference to harmonised standard for energy labelling of household dishwashers drafted in support of Delegated Regulation (EU) 2019/2017 and listed in Annex I to this Decision is hereby published in the *Official Journal of the European Union*.

The reference to harmonised standard on ecodesign of household dishwashers drafted in support of Regulation (EU) 2019/2022 and listed in Annex II to this Decision is hereby published in the *Official Journal of the European Union*.

Article 2

Implementing Decision (EU) 2021/913 is repealed.

Article 3

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 11 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Reference of the harmonised standard drafted in support of Delegated Regulation (EU) 2019/2017

EN 60436:2020

Electric dishwashers for household use – Methods for measuring the performance

EN 60436:2020/A11:2020

EN 60436:2020/AC:2020-06

EN 60436:2020/A12:2022

ANNEX II

Reference of the harmonised standard drafted in support of Regulation (EU) 2019/2022

EN 60436:2020

Electric dishwashers for household use – Methods for measuring the performance

EN 60436:2020/A11:2020

EN 60436:2020/AC:2020-06

EN 60436:2020/A12:2022

COMMISSION IMPLEMENTING DECISION (EU) 2023/1760**of 11 September 2023****on the recognition of the report including information on the typical greenhouse gas emissions from the cultivation of canola oilseed (rapeseed) in Australia under Article 31(3) and (4) of Directive (EU) 2018/2001 of the European Parliament and of the Council**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources ⁽¹⁾, and in particular Article 31(4) thereof,

Whereas:

- (1) Directive (EU) 2018/2001 sets out that biofuels, bioliquids, and biomass fuels have to save significant greenhouse gas emissions compared to fossil fuels so that they can be counted towards the targets set in that Directive. For that purpose, Article 29(10) sets specific emission savings thresholds for those fuels, and Article 31 sets out how to calculate the greenhouse gas emission savings from their use. When making those calculations, it is possible to use the default values set out in Annexes V and VI to Directive (EU) 2018/2001. Instead of the default values of greenhouse gas emissions from cultivating agricultural raw materials, it is possible to use typical values under some conditions. Those typical values, representing the average value in a specific area, may be reported to the Commission by Member States or third countries. The typical values may only be used if the Commission recognises them to be accurate.
- (2) On 18 May 2023, Australia sent the Commission the final report with data for the purposes of measuring the greenhouse gas emissions associated with the cultivating canola oilseed (rapeseed) typically produced in regions in Australia equivalent to NUTS 2 ⁽²⁾ regions of the Union, asking for the recognition of the accuracy of such data in line with Article 31(4) of Directive (EU) 2018/2001.
- (3) The Commission assessed the report and found that it contains accurate data for the purposes of measuring the greenhouse gas emissions associated with cultivating canola oilseed (rapeseed) typically produced in regions in Australia equivalent to NUTS 2 regions of the Union.
- (4) The measures provided for in this Decision are in accordance with the opinion of the Committee on the Sustainability of Biofuels, Bioliquids and Biomass Fuels,

HAS ADOPTED THIS DECISION:

Article 1

The report submitted for recognition to the Commission by Australia on 18 May 2023 contains accurate data for the purposes of measuring the greenhouse gas emissions associated with the cultivation of canola oilseed (rapeseed) typically produced in regions in Australia equivalent to NUTS 2 regions of the Union, pursuant to Article 31(4) of Directive (EU) 2018/2001. The summary of the report's data is set out in the Annex.

⁽¹⁾ OJ L 328, 21.12.2018, p. 82.

⁽²⁾ NUTS is a classification system for EU territorial units for statistics.

Article 2

This Decision is valid for a period of five years after the date of its entry into force. If the content of the report, as submitted for recognition to the Commission on 18 May 2023, changes in a way that might affect the basis of this Decision, such changes shall be notified to the Commission immediately. The Commission shall assess the notified changes to determine whether the report still provides accurate data for which it is recognised.

Article 3

The Commission may repeal this Decision if it has been clearly demonstrated that the report no longer contains accurate data for the purposes of measuring the greenhouse gas emissions associated with the cultivation of canola oilseed (rapeseed) produced in Australia.

Article 4

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 11 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Greenhouse gas emissions arising from the cultivation of canola oilseed (rapeseed) in the States of Australia (tonne CO₂-eq/tonne canola seed harvested on dry matter basis)

	Soil N ₂ O		Crop residue	Embedded			Fuel use	Fertiliser acidification	Seed	Total
	Direct	Indirect		Fertiliser	Pesticide	Lime				
New South Wales	0,060	0,015	0,056	0,229	0,038	0,002	0,065	0,041	0,002	0,508
Single purpose	0,057	0,011	0,066	0,248	0,047	0,002	0,075	0,044	0,002	0,554
Dual purpose	0,039	0,007	0,026	0,162	0,018	0,001	0,029	0,028	0,002	0,313
Irrigated	0,261	0,136	0,066	0,327	0,007	0,003	0,096	0,058	0,001	0,954
Victoria	0,023	0,009	0,062	0,221	0,036	0,002	0,050	0,040	0,002	0,444
Single purpose	0,024	0,009	0,065	0,226	0,038	0,002	0,052	0,041	0,002	0,458
Dual purpose	0,017	0,006	0,030	0,161	0,017	0,001	0,024	0,029	0,002	0,288
Queensland	0,061	0,008	0,063	0,239	0,054	0,002	0,167	0,043	0,003	0,641
South Australia	0,016	0,004	0,059	0,214	0,068	0,002	0,062	0,039	0,002	0,466
Single purpose	0,012	0,002	0,061	0,216	0,071	0,002	0,064	0,039	0,002	0,469
Dual purpose	0,009	0,001	0,028	0,155	0,032	0,001	0,029	0,028	0,002	0,285
Irrigated	0,232	0,125	0,061	0,288	0,007	0,003	0,096	0,052	0,001	0,865
Western Australia	0,014	0,003	0,058	0,225	0,030	0,002	0,069	0,037	0,002	0,441
Single purpose	0,014	0,003	0,059	0,225	0,031	0,002	0,069	0,037	0,002	0,441
Dual purpose	0,010	0,002	0,023	0,159	0,012	0,001	0,027	0,026	0,002	0,263
Tasmania*	0,240	0,127	0,057	0,298	0,013	0,003	0,079	0,054	0,001	0,873

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