AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF

S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate

AS A SUBSTANCE OF VERY HIGH CONCERN

under Articles 57 and 59 of Regulation (EC) 1907/2006

Adopted on 14 December 2021

This agreement concerns

S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate

EC number: 401-850-9

CAS number: 255881-94-8

Structural formulae:

where R = isopropyl/isobutyl/2-ethylhexyl

The Member State Committee agreed that:

1. **S-(tricyclo[5.2.1.0^{2,6}]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate is a substance under Article 57 (d) of Regulation (EC) 1907/2006 (REACH), which is persistent, bioaccumulative and toxic (PBT) in accordance with the criteria and provisions set out in Annex XIII of REACH.**

2. **S-(tricyclo[5.2.1.0^{2,6}]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate must be added to the Candidate list of substances of very high concern**.

Annex 1: Scientific evidence of persistent, bioaccumulative and toxic (PBT) properties in accordance with the criteria and provisions set out in Annex XIII of Regulation (EC) 1907/2006 (REACH)

The information below is based on Support Document (Member State Committee, 14 December 2021)

A weight-of-evidence determination according to the provisions of Annex XIII of REACH has been used to identify S-(tricyclo[5.2.1.$0^{2,6}$]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate (referred to as '**EC 401-850-9**' in this document) as PBT. All available information such as the results of standard tests, modelling and QSAR results was considered together in a weight-of-evidence approach. EC 401-850-9 is a substance that consists of 6 homologous groups of O,O',S-trialiphatic dithiophosphates**.** This PBT assessment of EC 401-850-9 is focused on the properties of isopropyl-isopropyl (**ip-ip**) constituents as these constituents are the most relevant ones with regard to their PBT profile.

Persistence

Detailed analysis of the available data from the biodegradation simulation study in fresh water (OECD TG 309) pointed out that the test item isopropyl-isopropyl (ip-ip) constituents degrade very slowly in fresh water, exhibiting a half-life of more than 200 days. The outcome of the ready biodegradation screening studies performed on EC 401-850-9 support the findings of the simulation study as EC 401-850-9 screens as potentially P/vP.

Finally, since EC 401-850-9 contains ip-ip constituents with P/vP properties at a concentration ≥ 0.1 % (w/w), it is concluded that EC 401-850-9 meets both the 'persistence' (**P**) (degradation half-life in water > 40 days) and 'very persistent' (**vP**) (degradation half-life in water > 60 days) criteria in accordance with Annex XIII, points 1.1.1 (b) and 1.2.1 (a), of the REACH Regulation.

Bioaccumulation

Based on the results from an experimental aquatic bioaccumulation study (OECD TG 305C) with three constituents of EC 401-850-9, lipid normalised steady-state bioconcentration factors (**BCF**) of 3794 L/kg and 2403 L/kg were determined for the isopropyl-isopropyl (ip-ip) and isobutyl-isobutyl (**ib-ib**) constituents, respectively. These BCF values represent a less conservative scenario as a possible growth dilution cannot be accounted for in steady-state BCF calculations. Modelling data support findings from experimental data on bioaccumulation of ip-ip and ib-ib constituents of EC 401-850-9. Consequently, it is concluded that isopropyl-isopropyl (ip-ip) and isobutyl-isobutyl (ib-ib) constituents meet the 'bioaccumulation' criterion (B) (BCF value > 2000 L/kg) of REACH Annex XIII.

Finally, since EC 401-850-9 contains isopropyl-isopropyl (ip-ip) and isobutyl-isobutyl (ib-ib) constituents with B properties at a concentration ≥ 0.1 % (w/w), it is concluded that EC 401-850-9 meets the 'bioaccumulation' criterion (**B**) in accordance with Annex XIII, point 1.1.2, of the REACH Regulation.

Toxicity

In the 21 day long-term immobilisation and reproduction test with *Daphnia magna* that was performed on EC 401-850-9 with predominantly the isopropyl-isopropyl constituents, a lowest observed effect concentration (**LOEC**) of 5.9 µg/L and a no observed effect

concentration (**NOEC**) of 1.8 µg/L was determined. The NOEC is less than 0.01 mg/L, which is the threshold for T laid down in Annex XIII of REACH. Consequently, it is concluded that EC 401-850-9 and isopropyl-isopropyl (ip-ip) constituents meet the 'toxicity' criterion (**T**) (NOEC < 0.01 mg/L) in accordance with Annex XIII, point 1.1.3 (a), of the REACH Regulation.

Overall conclusion

In conclusion, as the isopropyl-isopropyl (ip-ip) constituents meet the PBT criteria and their relative concentration in EC 401-850-9 largely exceeds 0.1% (w/w), EC 401-850-9 is identified as a PBT substance according to Article 57(d) of the REACH Regulation.

Annex 2: Procedure

1. On 27 August 2021, Belgium presented a proposal under Article 59(3) and Annex XV of the REACH Regulation on identification of EC 401-850-9 as a substance which satisfy the criteria of Article 57 (d) REACH.
2. On 3 September 2021, the Annex XV dossier was circulated to Member States and the Annex XV report was made available to interested parties on the ECHA website as required by Articles 59(3) and 59(4).
3. EC 401-850-9 received comments from both Member States and interested parties on the proposal.
4. On 17 November 2021, the dossier was referred to the Member State Committee (MSC) and discussed in the MSC meeting on 14-15 December 2021.