



HAZARD ASSESSMENT OUTCOME DOCUMENT

for

**2,5-Furandione, dihydro-, mono-C15-20-
alkenyl derivs.**

EC No 272-221-2

CAS No 68784-12-3

Member State(s): Norway

Dated: 30 March 2015

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1. HAZARD SUBJECT TO ASSESSMENT

2,5-Furandione, dihydro-, mono-C15-20-alkenyl derivs. was originally selected for hazard assessment in order to clarify suspected hazard properties:

PBT/vPvB

2. OUTCOME OF HAZARD ASSESSMENT

The available information on the substance and the hazard assessment conducted has led the assessing Authority to the following considerations, as summarised in the table below.

Hazard Assessment Conclusion	Tick box
According to the authority's assessment the substance does not have PBT/vPvB properties based on the currently available information.	X
According to the authority's assessment the substance has PBT/vPvB properties.	
According to the authority's assessment further information would be needed to confirm the PBT/vPvB properties but follow-up work is not relevant or carried out at present.	

This outcome is based on the REACH and CLP data as well as other available relevant information.

3. BASIS FOR REASONING¹

Persistence: There is rapid hydrolysis of the UVCB substance 2,5-Furandione, dihydro-, mono-C15-20-alkenyl derivatives into alkenyl succinic acids salts based on OECD 111 Test Guideline performed at 20 degrees Celsius. The rapid hydrolysis is assumed to cover the constituents hexadecenyl succinic anhydride, octadecenyl succinic anhydride and maleic anhydride which are assumed to transform based on basic chemistry information on reactivity of this kind of anhydrides into their acid forms. These are considered as readily biodegradable based on experimental data and QSARs predictions. For the constituents hexadecene and octadecene conflicting biodegradation test results exists, but they are considered as biodegradable based on experimental data and QSARs.

Bioaccumulation: No clear conclusion on the bioaccumulation potential of 2,5-Furandione, dihydro-, mono-C15-20-alkenyl derivatives can be drawn. Some of its constituents (hexadecene and octadecene), might be very bioaccumulative based on QSARs, however BCF values are contradicting and metabolisation has not been taken into account. Likewise hexadecenyl succinic anhydride is predicted to be bioaccumulative but it is assumed to hydrolyse rapidly into predicted non-bioaccumulative hexadecenyl succinic acid. Octadecenyl succinic acid is not bioaccumulative based on experimental data. No further assessment of bioaccumulation is considered necessary due to non-persistence of the remaining constituents, octadecenyl succinic anhydride and maleic anhydride.

Toxicity: Based on available short-term and long-term experimental data for 2,5-Furandione, dihydro-, mono-C15-20-alkenyl derivatives and its constituents the T criterion is not considered to be met concerning ecotoxicity. Assessment based on information on toxicity to human health was not carried out.

¹Assessments of PBT properties are based on Annex XIII to the REACH Regulation.