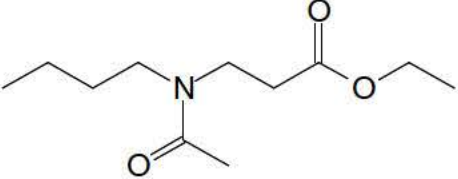


Section A2 Identity of Active Substance

Subsection (Annex Point)

Official
use only

2.1	Common name (IIA2.1)	IR3535®, Ethyl butylacetylaminopropionate			
2.2	Chemical name (IIA2.2)	<i>Ethyl 3-[N-acetyl-N-butyl] amino propionate</i> (IUPAC) beta-alanine, N-acetyl-N-butyl-, ethyl ester (CA)			
2.3	Manufacturer's development code number(s) (IIA2.3)	IR3535®			
2.4	CAS No and EC numbers (IIA2.4)				
2.4.1	CAS-No	52304-36-6			
	Isomer 1	No isomers			
	Isomer n				
2.4.2	EC-No	257-835-0			
	Isomer 1	No isomers			
	Isomer n				
2.4.3	Other	CIPAC No.: 667			
2.5	Molecular and structural formula, molecular mass (IIA2.5)				
2.5.1	Molecular formula	C ₁₁ H ₂₁ NO ₃			
2.5.2	Structural formula				
2.5.3	Molecular mass	215.29 g/mol			
2.6	Method of manufacture of the active substance (IIA2.1)	See confidential version of this document.			
2.7	Specification of the purity of the active substance, as	g/kg	g/l	% w/w	% v/v
		≥ 990	not applicable	≥ 99	not applicable

Section A2**Identity of Active Substance**

- 2.8 Identity of impurities and additives, as appropriate (IIA2.8) see separate standard format
- 2.8.1 Isomeric composition No isomers
- 2.9 The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9) Synthetic product

Evaluation by Competent Authorities

Identity of Active Substance

EVALUATION BY RAPPORTEUR MEMBER STATE**Date****Materials and methods****Conclusion****Reliability****Acceptability****Remarks****COMMENTS FROM .RMS AFTER THE TM****Date***November 2010***Results and discussion****Conclusion***the correct IUPAC-name for the active substance is Ethyl 3-[N-acetyl-N-butyl] amino propionate***Reliability****Acceptability****Remarks**

Section A2.8**Identity of impurities and additives (active substance)**

Annex Point IIA2.8

fill in one form for each impurity/additive

See confidential version of this document.

Section A2.10**Exposure data in conformity with Annex VIIA to
Council Directive 92/32/EEC (OJ No L, 05.06.1992,
p. 1) amending Council Directive 67/548/EEC**

Annex Point IIA2.10

SubsectionOfficial
use only**2.10.1 Human exposure
towards active
substance****2.10.1.1 Production**i) Description of
process

See confidential version of this document.

ii) Workplace
description

The whole reaction process (including loading of raw materials) is carried out in a closed device. All substance related occupational limit concentrations are far below critical data defined by legal regulations (MAK1 / TRK2 values). Potential human exposure is only possible during loading and cleaning/service processes. All handling with respect to these processes are carried out using personal protection measures, which are related to the respective task (up to full personal protection for special cleaning and service tasks).

1 MAK = maximum workplace concentration according to German legislation

2 TRK = technical exposure limit

iii) Inhalation
exposure

See ii) Workplace description

iv) Dermal
exposure

See ii) Workplace description

**2.10.1.2 Production of the
formulated
product**

The formulated product is a model formulation therefore exposure data have not been provided. Production in extremely small amounts for study purposes. However, in modern formulation plants typically automated equipment is used to add the formulation ingredients and to fill the formulated product into the respective vessels (closed systems). The workers (trained professionals) usually wear personal protective equipment (e.g. gloves). The exposure during the formulation task should be negligible.

Section A2.10**Annex Point IIA2.10****Exposure data in conformity with Annex VIIA to
Council Directive 92/32/EEC (OJ No L, 05.06.1992,
p. 1) amending Council Directive 67/548/EEC**

2.10.1.3 Intended use(s)	For details please refer to Document IIB, Chapter 3
1. Professional Users	Not relevant
2. Non-professional users (general public)	
via inhalational contact	For details please refer to document II B Chapter 3.
via skin contact	For details please refer to document II B Chapter 3
3. Secondary exposure	
inhalation of volatilized residues	For details please refer to document II B Chapter 3
4. indirect via environment	Not relevant.
via drinking water	Active substance is not expected to be found in drinking water. For details please refer to document II B Chapter 3.
via food	Active substance is not intended to be used during food production, food processing and in areas where food is transported and, stored. This is also the case for feeding stuffs. Thus, humans are not expected to be exposed to Active substance via food.
2.10.2 Environmental exposure towards active substance	
2.10.2.1 Production	
(i) Releases into water	In the Insect Repellent 3535® process several washes with brine (water plus salts) is performed. The water phase is transferred to the Biological Waste Water Treatment Plant. [REDACTED] [REDACTED] [REDACTED] Waste water: [REDACTED] (average per working day). The maximum concentration of Insect Repellent 3535® in waste water before being bio-treated is less than 10 ppm. [REDACTED] [REDACTED]
(ii) Releases into air	The product is purified by distillation under vacuum. Distillation devices are equipped with brine traps at -15°C to avoid release of volatile compounds to the air. The release of organic compounds during the production process to exhaust air is around [REDACTED]. It is supposed that these are mostly volatile compounds.
(iii) Waste disposal	Organic liquid waste is collected and delivered to approved third parties for incineration. [REDACTED] [REDACTED] [REDACTED]

Table A2.10: Workplace exposure / Inhalation exposure (use additional terminology from the TNsGs on Human exposure)

Exposure scenario	Workplace operation	PPE	Year(s) of measurement	Number of measurements	Type of measurements	Exposure concentration
<i>Production¹⁾</i>	<i>Emptying, filling, weighing</i>	<i>Gloves</i>			<i>personal, TWA</i>	
<i>Formulation¹⁾</i>	<i>Cleaning</i>	<i>Protective coverall</i>			<i>area, short-term</i>	
<i>Application MG../PT..²⁾</i>	<i>Brushing</i>	<i>Gloves, goggles</i>				

1) All substances related to occupational limit concentrations are far below critical data defined by legal regulations.

2) Human exposure to IR3535® during application of products containing IR3535® was assessed according to the TNsG on human Exposure. For details please refer to Document IIA, Chapter 8.2.